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15 ATTORNEYS FOR PLAINTIFFS

16 UNITED STATES DISTRICT COURT
17 NORTHERN DISTRICT OF CALIFORNIA
18

19 TAMARA MOORE, GRETA L. ERVIN, RAFF
20 ARANDO, NICHOLS SMITH, RENEE
EDGREN and CYNTHIA WELTON, on behalf
of themselves and all others similarly situated,

21 Plaintiffs,

22 v.
23

24 MARS PETCARE US, INC.; NESTLE
PURINA PETCARE COMPANY; HILL'S PET
NUTRITION, INC.; PETSMART, INC.;
25 MEDICAL MANAGEMENT
INTERNATIONAL, INC. D/B/A BANFIELD
26 PET HOSPITAL; BLUEPEARL VET, LLC,

27 Defendants.
28

Case No. 3:16-cv-7001

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

1 Plaintiffs (collectively referred to herein as "Plaintiffs" or "Plaintiffs/Class
2 Representatives"), individually and on behalf of others similarly situated, file this Class Action
3 Complaint against Defendants Mars Petcare US, Inc. ("Mars"); Nestle Purina Petcare Company
4 ("Purina"); Hill's Pet Nutrition, Inc. ("Hill's"); PetSmart, Inc. ("PetSmart"); Medical Management
5 International, Inc. d/b/a Banfield Pet Hospital ("Banfield Pet Hospital"); and BluePearl Vet, LLC
6 ("Blue Pearl Vet Hospital") (collectively, "Defendants"), and allege as follows:

7 **I. GENERAL OVERVIEW**

8 1. Defendants individually and collectively exercise significant market power in the
9 United States market for dog and cat food ("pet food"), which is the relevant market for purposes
10 of the federal antitrust claims asserted herein.

11 2. Defendants manufacture, market, and sell one or more lines of pet food that are
12 sold at retail by "prescription."

13 3. The prescription to purchase the prescription pet food is written by a veterinarian,
14 as would be done for a prescription drug for a dog or cat.

15 4. The prescription-authorization requirement enables Defendants to market and sell
16 prescription pet food at well above market prices that would not otherwise prevail in the absence
17 of the prescription-authorization requirement.

18 5. Other than as imposed by Defendants, however, the prescription pet food is not
19 required to be sold by prescription.

20 6. Defendants' prescription pet food contains no drug or other ingredient not also
21 common in non-prescription pet food.

22 7. Defendants' marketing, labeling, and/or sale of prescription pet food is deceptive,
23 collusive, and in violation of federal antitrust law and California consumer-protection law.

24 8. Defendants are engaged in an anticompetitive conspiracy to market and sell pet
25 food as prescription pet food to consumers at above-market prices that would not otherwise prevail
26 in the absence of their collusive prescription-authorization requirement.

27 9. Retail consumers, including Plaintiffs, have overpaid and made purchases they
28 otherwise would not have made on account of Defendants' abuse and manipulation of the

1 "prescription" requirement. Plaintiffs bring this putative class action for violation of United States
2 antitrust law on behalf of themselves and all those similarly situated purchasers of prescription pet
3 food from Defendants, and seek redress in the form of damages, restitution, injunctive relief, and
4 all other relief this Court deems just and proper. Plaintiffs bring this putative class action for
5 violation of California consumer-protection law on behalf of themselves and all those similarly
6 situated purchasers of prescription pet food manufactured by Defendant manufacturers, and seek
7 redress in the form of damages, restitution, injunctive relief, and all other relief this Court deems
8 just and proper.

9 **II. FACTUAL BACKGROUND**

10 **A. Defendants individually and collectively exercise significant market power in**
11 **the United States market for pet food.**

12 10. Manufacturing, producing, marketing, advertising, distributing, and selling pet food
13 is an approximately \$24 billion per year industry in the United States. *See* American Pet Products
14 Association Pet Industry Market Size & Ownership Statistics, attached hereto as Exhibit A.

15 11. Most of the approximately 163.6 million domestic cats and dogs in the United
16 States derive their daily nutritional content from commercial pet food. *See* Humane Society of the
17 U.S. Pet Ownership Estimates, attached hereto as Exhibit B.

18 12. Hill's, a Delaware corporation with a principal place of business in Kansas, is in the
19 business of manufacturing, producing, marketing, advertising, distributing, and/or selling dog and
20 cat food under various brands or labels, including, but not limited to, the "prescription only" pet
21 food Hill's "Prescription Diet." In 2015, Hill's was the fourth largest seller of pet food in the
22 world, with over \$1 billion in sales. *See* petfoodindustry.com Infographic: World's Top Pet Food
23 Companies 2015, attached hereto as Exhibit C.

24 13. Purina, a Missouri corporation with a principal place of business in Missouri, is in
25 the business of manufacturing, producing, marketing, advertising, distributing, and/or selling dog
26 and cat food under various brands or labels, including, but not limited to, the "prescription only"
27 pet food Purina "Pro Plan Veterinary Diets." In 2015, Purina was the second largest seller of pet
28 food in the world, with over \$11 billion in sales. *See* Exhibit C.

1 14. Mars, a Delaware corporation with a principal place of business in Tennessee, is in
2 the business of manufacturing, producing, marketing, advertising, distributing, and/or selling dog
3 and cat food under various brands or labels, including, but not limited to, the "prescription only"
4 pet foods Royal Canin "Veterinary Diet" and Iams "Veterinary Formula." In 2015, Mars was the
5 largest seller of pet food in the world, with over \$17 billion in sales. *See Exhibit C.*

6 15. PetSmart, a Delaware corporation with a principal place of business in Arizona, is
7 the largest pet goods retailer in the United States. Approximately 900 of PetSmart's approximately
8 1,145 nationwide stores include an onsite "Banfield Pet Hospital." Through these locations,
9 PetSmart sells Royal Canin "Veterinary Diet," Hill's "Prescription Diet," and Purina "Pro Plan
10 Veterinary Diets" pet foods to customers presenting a prescription from a veterinarian. PetSmart
11 also sells other foods manufactured by each Defendant manufacturer.

12 16. Banfield Pet Hospital, a Delaware corporation with a principal place of business in
13 Oregon, is the largest veterinary chain in the United States, operating veterinary clinics at
14 PetSmart locations, and at standalone locations, and employing approximately 3,200 veterinarians.
15 Banfield Pet Hospitals sell Prescription Pet Food to customers presenting a prescription from a
16 veterinarian or prescribed such foods by a Banfield Pet Hospital veterinarian.

17 17. Mars owns approximately 79% of Banfield Pet Hospital, and PetSmart owns
18 approximately 21%.

19 18. Blue Pearl Vet Hospital, a Florida corporation with a principal place of business in
20 Florida, is the largest chain of animal specialty and emergency care clinics in the United States,
21 with approximately 50 locations and 600 veterinarians. Blue Pearl Vet Hospitals sell Prescription
22 Pet Food to consumers prescribed such foods by a Blue Pearl Vet Hospital veterinarian.

23 19. Mars owns Blue Pearl Vet Hospital.

24 20. As an owner of Banfield Pet Hospital and the owner of Blue Pearl Vet Hospital,
25 Mars employs approximately 7.5% of the companion-animal veterinarians in the United States.
26 *See American Veterinary Medical Association Market Research Statistics, attached hereto as*
27 Exhibit D.

28

1 **B. Defendants manufacture, market, and sell one or more lines of pet food that**
2 **are sold at retail by "prescription."**

3 21. "Prescription only" pet food is marketed and sold across the United States.

4 22. "Prescription only" pet food sales comprise approximately 5% of all pet food sales
5 in the United States.

6 23. Defendants misrepresent "prescription only" pet food in a variety of ways, further
7 discussed below, to be: (a) a substance medically necessary to health; (b) a drug, medicine, or
8 other controlled ingredient; (c) a substance that has been evaluated by the Food and Drug
9 Administration ("FDA") as a drug; (d) a substance as to which the manufacturer's representations
10 regarding intended uses and effects have been evaluated by the FDA; and/or (e) a substance
11 legally required to be sold by prescription.

12 24. Defendants Mars, Hill's, and Purina each manufacture pet food for which a
13 prescription is required.

14 25. Defendant manufacturers sell several different prescription pet foods, a
15 demonstrative list of which is attached hereto as Exhibit E. Those pet foods listed on Exhibit E,
16 and all similar "prescription only" pet foods manufactured, produced, marketed, advertised,
17 distributed, and/or sold by Defendants, are referred to collectively herein as "Prescription Pet
18 Food," and the labels borne by the foods identified on Exhibit E are incorporated herein by
19 reference.

20 **C. The prescription to purchase Prescription Pet Food is written by a**
21 **veterinarian, as would be done for a prescription drug for a dog or cat.**

22 26. Most pet owners are familiar with the heartfelt concern and fear that accompanies
23 some trips to the veterinarian, as well as the willingness to follow doctor's orders to, and
24 sometimes beyond, the fullest extent the owner can afford.

25 27. Pursuant to Defendants' marketing schemes, a veterinarian may prescribe a
26 Prescription Pet Food for sale to pet owners.

27 28. In order that this prescription may be fulfilled, a veterinarian may (a) sell
28 Prescription Pet Food directly to the retail consumer with whom the veterinarian-client-patient

1 relationship exists, or (b) provide the consumer a written prescription that can be presented at a
2 business that sells Prescription Pet Food, such as Banfield Pet Hospital locations, Blue Pearl Vet
3 Hospital locations, and PetSmart stores with an onsite veterinarian. That is, Defendants restrict
4 the sale of Prescription Pet Food at retail to those with a prescription from a veterinarian.

5 29. The prescription necessary to purchase Prescription Pet Food is hereinafter referred
6 to as the "Prescription Authorization."

7 30. For some pets, Prescription Pet Food may be prescribed only for a finite period of
8 time, while, for others, Prescription Pet Food may be prescribed indefinitely, such as for the
9 remainder of the pet's life.

10 31. To a reasonable retail consumer, Prescription Pet Food is prescribed and purchased
11 in the exact same manner as a prescription drug for a dog or cat—by veterinarian's orders.

12 **D. The Prescription Authorization requirement enables Defendants to market**
13 **and sell Prescription Pet Food at well above-market prices that would not**
14 **otherwise prevail in the absence of the Prescription Authorization.**

15 32. The American public, and Plaintiffs, as reasonable consumers, have a deep-rooted
16 sense of the role of the prescription in healthcare and well-being.

17 33. The American public, and Plaintiffs, as reasonable consumers, associate
18 prescription fulfillment with following doctor's orders.

19 34. Meriam Webster's Learner's Dictionary provides simple definitions for the word
20 "prescription" including: "a written message from a doctor that officially tells someone to use a
21 medicine, therapy, etc."; and "a medicine or drug that a doctor officially tells someone to use."

22 35. The American public, and Plaintiffs, as reasonable consumers, reasonably expect
23 and believe that a substance that requires a prescription to obtain, for a human or an animal, is: (a)
24 a substance medically necessary to health; (b) a drug, medicine, or other controlled ingredient; (c)
25 a substance that has been evaluated by the FDA as a drug; (d) a substance as to which the
26 manufacturer's representations regarding intended uses and effects have been evaluated by the
27 FDA; and/or (e) a substance legally required to be sold by prescription.

28 36. For instance, in 1997, John Steel, then the recently retired senior vice president of
global marketing and sales at Colgate (of which Hill's is a wholly-owned subsidiary) was quoted

1 by the Wall Street Journal as stating with regard to Prescription Pet Food: "It's just like taking
2 drugs: You go to the doctor and he prescribes something for you and you don't much question
3 what the doctor says. It's the same with animals." See Exhibit F.

4 37. In addition to Prescription Pet Food, Defendants also manufacture, produce,
5 market, advertise, distribute, and/or sell one or more non-prescription pet foods, which are
6 marketed for the same or similar conditions as Prescription Pet Foods and are sold at significantly
7 lower prices than Prescription Pet Foods.

8 38. Except for the Prescription Authorization and other practices of the Defendants
9 described herein, there is no material difference between Prescription Pet Food and non-
10 prescription pet food. To the extent there are any differences, they are not sufficient to explain the
11 price disparity between Prescription Pet Food and non-prescription pet food.

12 39. Prescription Pet Food is sold at significantly higher prices than comparable pet
13 food, which Plaintiffs and other similarly situated consumers pay due to false marketing and
14 labeling indicating that Prescription Pet Food is: (a) a substance medically necessary to health; (b)
15 a drug, medicine, or other controlled ingredient; (c) a substance that has been evaluated by the
16 FDA as a drug; (d) a substance as to which the manufacturer's representations regarding intended
17 uses and effects have been evaluated by the FDA; and/or (e) a substance legally required to be
18 sold by prescription.

19 **E. Other than as imposed by Defendants, however, Prescription Pet Food is not**
20 **required to be sold by prescription.**

21 40. The FDA regulates foods and drugs, including pet foods and drugs.

22 41. The FDA does not require that Prescription Pet Food be sold by prescription.

23 42. No other governmental body or agency requires that Prescription Pet Food be sold
24 by prescription.

25 43. The Prescription Authorization is self-imposed by Defendant manufacturers and
26 those acting in concert with them.

1 44. Others, including PetSmart, Banfield Pet Hospital, and Blue Pearl Vet Hospital,
2 abide by and perpetuate the Prescription Authorization requirement as they likewise benefit and
3 profit from above-market prices for Prescription Pet Food.

4 45. Although the message that Prescription Pet Food requires a prescription is repeated
5 throughout Defendants' distribution, marketing, and/or advertising, that message is false.
6 Prescription Pet Food is not legally required to be sold by prescription.

7 **F. Prescription Pet Food contains no drug or other ingredient not also common**
8 **in non-prescription pet food.**

9 46. Prescription Pet Food:

10 a. has not been subjected to the FDA process for evaluating the quality of drug
11 ingredients and manufacturing processes;

12 b. has not been subjected to the FDA process for evaluating the efficacy of
13 claims and propriety of representations;

14 c. does not contain any ingredients listed as a drug in the FDA's "Green
15 Book," a publication listing all approved animal drugs;

16 d. does not appear as a drug in the Green Book;

17 e. does not contain any drug approved by the FDA; and

18 f. does not bear the mandatory legend borne by those items required by the
19 FDA to be sold by prescription (i.e. "Caution: Federal law restricts this drug to use by or on the
20 order of a licensed veterinarian.").

21 47. Prescription Pet Food is made of the same ingredients contained in common pet
22 foods.

23 **G. Defendants' marketing, labeling, and/or sale of Prescription Pet Food is**
24 **deceptive, collusive, and in violation of federal antitrust law and California**
consumer protection law.

25 48. Defendants have profited from the deep-rooted understanding of the American
26 public, including Plaintiffs, with respect to the necessity of complying with the prescriptions of
27 medical professionals for animal health.
28

1 49. The Prescription Authorization and Defendants' marketing regarding Prescription
2 Pet Food are not pursuant to a legal prescription regime, but rather a false and misleading
3 marketing scheme to which all Defendants adhere.

4 50. In addition to requiring that the food be sold pursuant to the Prescription
5 Authorization, Defendants make further material representations, expressly and/or implicitly, that
6 Prescription Pet Food is: (a) a substance medically necessary to health; (b) a drug, medicine, or
7 other controlled ingredient; (c) a substance that has been evaluated by the FDA as a drug; (d) a
8 substance as to which the manufacturer's representations regarding intended uses and effects have
9 been evaluated by the FDA; and/or (e) a substance legally required to be sold by prescription.

10 51. For example:

11 a. As to its Royal Canin "Veterinary Diet" line, Mars makes advertising and
12 marketing representations to consumers including that its Royal Canin "Veterinary Diet"
13 Prescription Pet Food "support[s] a wide range of health issues such as: Urinary Health, Skin and
14 Food Allergies, Diabetes, Digestive Support, Liver Health, Joint Support, Illness and Surgery
15 Recovery Support, Renal Health, Weight Management, and Cardiac Health." Further, bags of
16 Royal Canin "Veterinary Diet" Prescription Pet Food state that the food is "Veterinary Exclusive."
17 *See Exhibit G* (consisting of an image of a bag of Royal Canin Veterinary Diet Calm cat food).

18 b. As to its Iams "Veterinary Formula" line, Mars sells Prescription Pet Food
19 purportedly meant to treat or prevent conditions, including, but not limited to, those related to the
20 following: "joint," "skin & coat," "intestinal," "glucose and weight control," "weight
21 loss/mobility," "renal," and "urinary." Bags of Iams "Veterinary Formula" state that the food is
22 "prescribed and sold by veterinarians" and "[a]uthorized by prescription and sold only through
23 veterinarians." Further, bags of Iams "Veterinary Formula" also state: "Your veterinarian will
24 recommend the Iams Veterinary Formula that best matches the health needs of your [pet]. When
25 deemed appropriate by your veterinarian, your [pet] may be transitioned to an appropriate Iams
26 Premium Protection®, Iams® or Eukanuba® [pet] formula." *See Exhibit H* (consisting of images
27 of various portions of a bag of Iams Veterinary Formula Intestinal Plus prescription dog food).

28

1 c. As to its Purina "Pro Plan Veterinary Diets" line, Purina sells Prescription
2 Pet Food purportedly meant to treat or prevent conditions, including, but not limited to, those
3 related to the following: "food sensitivities," "GI upset," "overweight management," "joint
4 mobility," "colitis and diabetes," "dietetic management," "urinary stones," "Feline Lower Urinary
5 Tract Disease," "kidney conditions," "dental health," "skin inflammation," and "diarrhea." In
6 addition, bags of Purina "Pro Plan Veterinary Diets" are branded with an "Rx" symbol. *See*
7 Exhibit I (consisting of an image of a portion of a bag of Purina Pro Plan Veterinary Diet Urinary
8 St/Ox prescription cat food).

9 d. As to its Hill's "Prescription Diet" line, Hill's sells Prescription Pet Food
10 purportedly meant to treat or prevent conditions, including, but not limited to, those related to the
11 following: "weight management," "digestive care," "food sensitivities," "urinary care," "kidney
12 care," "dental care," "aging care," "glucose management," "heart care," "joint care," "liver care,"
13 "skin sensitivity," "thyroid care," and "urgent care." Hill's further represents: "No matter what
14 health issues your dog is facing, our alliance with veterinarians puts us in a unique position to find
15 a solution. Ask your vet how the Prescription Diet® dog foods can help his weight, mobility,
16 kidney, digestive, urinary and skin and coat health." In addition, bags of Hill's "Prescription Diet"
17 represent that the contents are "Clinical Nutrition" and bear an image of a stethoscope. *See*
18 Exhibit J (consisting of an image of a portion of a bag of Hill's Prescription Diet Digestive /
19 Weight / Glucose Management w/d dog food).

20 52. The Prescription Authorization and Defendant manufacturers' advertising and
21 marketing statements regarding Prescription Pet Food misrepresent that Prescription Pet Food is:
22 (a) a substance medically necessary to health; (b) a drug, medicine, or other controlled ingredient;
23 (c) a substance that has been evaluated by the FDA as a drug; (d) a substance as to which the
24 manufacturer's representations regarding intended uses and effects have been evaluated by the
25 FDA; and/or (e) a substance legally required to be sold by prescription.

26 53. Consumers, including Plaintiffs, would not purchase Prescription Pet Food, or,
27 would not Purchase Prescription Pet Food when priced so excessively relative to similar no-
28 prescription-required pet foods, if not for the misleading marketing described herein.

1 54. While Prescription Pet Food contains no drug, in the pursuit of profit, Defendants
2 market, label, and/or sell it as if a prescription is required. In so doing, and by failing to comply
3 with the regulatory requirements referenced below, Defendants have manufactured and/or sold to
4 consumers misbranded substances.

5 55. For example, because it is marketed to diagnose, cure, mitigate, treat, or prevent
6 diseases or other conditions, Prescription Pet Food falls within the statutory definition of a drug
7 under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FD&C Act").

8 56. Because Prescription Pet Food is an article used for food for animals, Prescription
9 Pet Food also meets the definition of food under the FD&C Act.

10 57. By analogy, a box of Cheerios would meet the statutory definition of a drug if it
11 were marketed to treat the flu (in humans or animals). In addition, because it would still be a box
12 of Cheerios, it would also meet the FD&C Act definition of food.

13 58. Pursuant to the FD&C Act, in general, new drugs are unsafe unless they have an
14 approved application, a conditional approval, or an index listing.

15 59. None of the Prescription Pet Foods is an approved or listed new drug; as such,
16 Prescription Pet Food, if a drug, is misbranded under the FD&C Act.

17 60. The FD&C Act also requires that all drug manufacturers register and list drugs with
18 the FDA.

19 61. None of the Prescription Pet Foods comply with the drug registration and listing
20 requirements of the FD&C Act; as such, Prescription Pet Food, if a drug, is misbranded.

21 62. The FD&C Act requires that any animal drug products be manufactured in
22 accordance with current good manufacturing practices applicable to drugs.

23 63. Not all of the Prescription Pet Foods comply with the current good manufacturing
24 practices applicable to drugs pursuant to the FD&C Act; as such, those Prescription Pet Foods, if
25 drugs, are misbranded.

26 ///

27 ///

28 ///

1 **H. Defendants are engaged in an anticompetitive conspiracy to market pet food**
2 **as prescription pet food to consumers at above-market prices that would not**
3 **otherwise prevail in the absence of their collusive Prescription Authorization**
4 **requirement.**

5 64. The United States market for pet food is dominated by Mars, Hill's, and Purina,
6 which collectively exercise market power in this market.

7 65. These Defendants are the primary producers of prescription pet food sold in the
8 United States, and sell and market their products in and through interstate commerce and
9 instrumentalities of interstate commerce.

10 66. For at least the four years next prior to the filing of this Complaint, all Defendants
11 have entered into a contract, combination, or conspiracy to raise, fix, stabilize, or peg prices for
12 Prescription Pet Food.

13 67. By selling deceptively labeled and marketed Prescription Pet Food at above-
14 market, non-competitive prices, all Defendants have engaged in similar, parallel conduct
15 evidencing their contract, combination, or conspiracy, in that they have engaged in similar
16 marketing and sales practices and programs to sell pet food as prescription pet food.

17 68. In addition, there are plus factors tending to exclude the possibility of independent
18 action and demonstrating the existence of a conscious commitment by Defendants to a common
19 scheme designed to achieve their unlawful objective.

20 69. The first such plus factor is the interlocking and common nature of the business
21 relationships among Defendants. Mars, which is the biggest seller of pet food and sells two of the
22 four Prescription Pet Food brands, is also the owner of the largest veterinarian hospital chain in the
23 United States, Blue Pearl Vet Hospital, which employs veterinarians writing prescriptions for
24 Prescription Pet Food. Mars also partners with the largest specialty pet retailer, PetSmart, in the
25 ownership of the largest veterinarian clinic chain, Banfield Pet Hospital, which employs
26 veterinarians writing prescriptions for Prescription Pet Food. PetSmart sells non-prescription pet
27 foods made by all Defendant manufacturers, and uses its relationship with Banfield to promote
28 and sell Prescription Pet Food. Blue Pearl Vet Hospital sells Prescription Pet Food. Through this

1 vertical integration and common ownership and control of distribution and prescription-writing for
2 Prescription Pet Food, Defendants are able effectively to implement their price-fixing agreement.

3 70. A second plus factor is Defendant manufacturers' participation in and use of an
4 industry trade association, the Pet Food Institute ("PFI"), to implement and perpetuate their price-
5 fixing agreement. Defendant manufacturers are all on PFI's board of directors and have used PFI's
6 auspices to promote their price-fixing agreement that Prescription Pet Food should be sold
7 ostensibly as a product subject to FDA regulation and the FD&C Act, but should not in fact be
8 regulated by the FDA or held to the FD&C Act. For example, the Defendant manufacturers,
9 through PFI, have joined together to urge the FDA that, although Prescription Pet Foods "are not
10 drugs" and "no drug registration or drug listing should be required," such products should
11 nevertheless "only be available to the public through licensed veterinarians with whom the
12 purchaser has a valid Veterinary-Client-Patient Relationship." See Exhibit K attached hereto.

13 71. A third plus factor is that each Defendant has acted contrary to its own individual,
14 independent self-interest in marketing and selling Prescription Pet Food. Specifically, each
15 Defendant has known and understood that it was engaging in deceptive practices that could not
16 succeed unless each other Defendant had agreed to engage in similar conduct. Thus, each
17 Defendant knew and understood that if even one Defendant acknowledged that no Prescription
18 Authorization was actually required or exposed the scheme, all would be forced to follow and the
19 scheme would fail, and each Defendant maintained a conscious commitment to abide by the
20 deceptive scheme. That all Defendants proceeded with the deceptive marketing practices, which
21 all knew could be exposed by any of them, tends to exclude the possibility of independent action
22 and is evidence of a conscious commitment to a common scheme to achieve an unlawful
23 objective.

24 72. A fourth plus factor is the structure of the pet food industry, which facilitates
25 collusion and impedes new entry to disrupt collusive arrangements. The Defendant manufacturers
26 are the primary three firms marketing Prescription Pet Food, in essence sharing a monopoly that
27 makes collusion practicable. In addition, the Defendant manufacturers have well-established and
28 entrenched distribution arrangements and relationships with Defendant PetSmart and veterinary

1 chains, which discourage and impede new entry for other potential manufacturers of Prescription
2 Pet Food. Collusion among the Defendant manufacturers is further attractive because of sunk
3 costs in manufacturing facilities, which cannot be recovered by new entrants if new entry is
4 unsuccessful, and the substantial fungibility of pet food.

5 73. This prescription pet food scheme is a conspiracy in restraint of trade among
6 Defendants to fix, raise, peg, and stabilize prices for Prescription Pet Food in *per se* violation of
7 Section 1 of the Sherman Antitrust Act, 15 U.S.C. §1. Alternatively, Defendants' agreement,
8 combination, and conspiracy violates Section 1 under the Rule of Reason or Quick Look Rule of
9 Reason, in that the anticompetitive effects of Defendants' concerted action overwhelmingly
10 outweigh procompetitive benefits, if any, in the United States market for pet food, and less
11 restrictive alternatives exist for the marketing of Defendants' pet food in the absence of collusion.

12 **III. PARTIES**

13 74. Plaintiff/Class Representative Tamara Moore ("Ms. Moore") is a resident of
14 Alameda County, State of California. She has a dog named Pugalicious. When Pugalicious had to
15 undergo surgery to remove kidney stones, Ms. Moore received a Prescription Authorization from
16 Pugalicious's veterinarian, located in Santa Clara County, for, and purchased, Hill's Prescription
17 Diet d/u food. This food is a Prescription Pet Food. Ms. Moore purchased the referenced
18 Prescription Pet Food from her veterinarian's office in Santa Clara County within the three years
19 next prior to the filing of this Complaint.

20 75. Plaintiff/Class Representative Raff Arando ("Mr. Arando") is a resident of San
21 Mateo County, State of California. Mr. Arando had a dog named Bella. When Bella gained
22 weight, Mr. Arando received a Prescription Authorization from Bella's veterinarian, located in San
23 Mateo County, for, and purchased, Hill's Prescription Diet w/d food. He later received a
24 Prescription Authorization for the same food from a Banfield Pet Hospital adjacent to a PetSmart
25 located in San Mateo County. This food is a Prescription Pet Food. Mr. Arando purchased the
26 referenced Prescription Pet Food from a PetSmart located in San Mateo County within the three
27 years next prior to the filing of this Complaint.

28

1 76. Plaintiff/Class Representative Greta L. Ervin ("Mrs. Ervin") is a resident of San
2 Diego County, State of California. Mrs. Ervin has a dog named Teddy. When Teddy became ill
3 with giardia (a diarrheal infection associated with microscopic parasites that is not uncommon in
4 dogs and cats), Mrs. Ervin received a Prescription Authorization from Teddy's primary-care
5 veterinarian, located in California, for, and purchased, Royal Canin Veterinary Diet
6 Gastrointestinal dry and wet dog food, and also received a Prescription Authorization from
7 Teddy's specialty veterinarian, located in California, for, and purchased, Royal Canin Veterinary
8 Diet Selected Protein Adult PV dry and wet dog food. Each of these foods is a Prescription Pet
9 Food. Mrs. Ervin purchased Prescription Pet Food from PetSmart and also from her veterinarian,
10 both located in California, within the three years next prior to the filing of this Complaint.

11 77. Plaintiff/Class Representative Nichols Smith ("Mr. Smith") is a resident of San
12 Luis County, State of California, and a former resident of Sonoma County, State of California.
13 Mr. Smith has a cat named Mimi, and, until recently, also had a cat named Neichi. When Mimi
14 and Neichi became overweight, Mr. Smith received a Prescription Authorization from the cats'
15 veterinarian, located in Sonoma County, for, and purchased Hill's Prescription Diet from the
16 veterinarian's clinic. Mr. Smith later moved to San Luis County, where he purchased the same
17 food from another veterinary clinic. This food is a Prescription Pet Food. Mr. Smith's purchases
18 were made within the three years next prior to the filing of this Complaint.

19 78. Plaintiff/Class Representative Renee Edgren ("Ms. Edgren") is a resident of the
20 City and County of San Francisco, State of California. Ms. Edgren has a dog named Barkley.
21 When Barkley experienced skin and coat problems, Ms. Edgren received a Prescription
22 Authorization from Barkley's veterinarian, located in San Mateo County, for, and purchased, Iams
23 Veterinary Skin & Coat Plus Response KO dog food. This food is a Prescription Pet Food. Ms.
24 Edgren purchased this food within the three years next prior to the filing of this Complaint.

25 79. Plaintiff/Class Representative Cynthia Welton ("Ms. Welton") is a resident of San
26 Mateo County, State of California. Ms. Welton has a dog named Kodiak. When Kodiak became
27 ill, Ms. Welton received a Prescription Authorization from Kodiak's veterinarian, located in San
28 Mateo County, for, and purchased, Hill's Prescription Diet k/d dog food. This food is a

1 Prescription Pet Food. Ms. Welton purchased this food within the three years next prior to the
2 filing of this Complaint.

3 80. As discussed above: Defendant Mars is a Delaware corporation with a principal
4 place of business in Tennessee; Defendant Purina is a Missouri corporation with a principal place
5 of business in Missouri; Defendant Hill's is a Delaware Corporation with a principal place of
6 business in Kansas; Defendant PetSmart is a Delaware corporation with a principal place of
7 business in Arizona; Defendant Banfield Pet Hospital is a Delaware corporation with a principal
8 place of business in Oregon; and Defendant Blue Pearl Vet Hospital is a Florida corporation with
9 a principal place of business in Florida.

10 **IV. JURISDICTION**

11 81. This Court has jurisdiction over this action pursuant to 15 U.S.C. §§ 15, 26, and 28
12 U.S.C. §§ 1331, 1337. It also has jurisdiction pursuant to 28 U.S.C. § 1332(d) because there are
13 more than 100 class members and the aggregate amount in controversy exceeds \$5,000,000.00,
14 exclusive of interest, fees, and costs, and at least one Class Member is a citizen of a state different
15 from at least one Defendant.

16 **V. INTRADISTRICT ASSIGNMENT**

17 82. Pursuant to Northern District of California Civil Local Rules 3-2 and 3-5,
18 assignment to the San Francisco or Oakland Division of the Northern District of California is
19 proper because a substantial number of the events or omissions that give rise to the claims asserted
20 by the Plaintiffs and Class Representatives occurred in the counties of Alameda, San Mateo, and
21 Sonoma.

22 **VI. CLASS ACTION ALLEGATIONS**

23 83. Plaintiffs/Class Representatives bring this action on behalf of themselves and all
24 other similarly situated persons pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3),
25 and/or (b)(1), (b)(2), and/or (c)(4). This action satisfies the numerosity, commonality, typicality,
26 adequacy, predominance, and superiority requirements of those provisions.

27
28

1 **A. The Classes.**

2 84. Plaintiffs/Class Representatives Mrs. Ervin and Mr. Arando seek to represent a
3 nationwide Class defined as all persons in the United States who purchased Prescription Pet Food
4 from PetSmart, Banfield Pet Hospital, Blue Pearl Vet Hospital, or any other Defendant, for the
5 purposes of Cause of Action I hereafter ("Nationwide Direct Purchaser Class").

6 85. Plaintiff/Class Representative Mrs. Ervin seeks to represent a California statewide
7 Class of all California residents who purchased Royal Canin Prescription Pet Foods from any
8 retailer in California, for the purposes of Causes of Action II–V hereafter ("Royal Canin California
9 Class").

10 86. Plaintiff/Class Representative Ms. Edgren seeks to represent a California statewide
11 Class of all California residents who purchased Iams Prescription Pet Foods from any retailer in
12 California, for the purposes of Causes of Action II–V hereafter ("Iams California Class").

13 87. Plaintiff/Class Representatives Ms. Moore, Mr. Arando, Ms. Welton, and Mr.
14 Smith seek to represent a California statewide Class of all California residents who purchased
15 Hill's Prescription Pet Foods from any retailer in California, for the purposes of Causes of Action
16 II–V hereafter ("Hill's California Class").

17 88. Excluded from the Classes are: (a) Defendants, any entity or division in which
18 Defendants have a controlling interest, and their legal representatives, officers, directors, assigns,
19 and successors; (b) the Judge to whom this case is assigned and the Judge's staff; (c) the attorneys
20 involved in this matter; (d) governmental entities; (e) those persons who have suffered personal
21 injuries or emotional distress as a result of the facts alleged herein; and (f) all persons or entities
22 that purchased Prescription Pet Food for resale. Plaintiffs reserve the right to amend the Class
23 definitions if discovery and further investigation reveal that any Class should be expanded,
24 divided into subclasses, or modified in any other way.

25 **B. The Classes satisfy the Rule 23 requirements.**

26 89. Members of each of the Classes are so numerous that joinder of all members is
27 impracticable. While the exact number of Class Members for each Class is currently unknown,
28 and can only be ascertained through appropriate discovery, the members of the Classes are likely

1 to number at least in the thousands, and the disposition of the Class Members' claims in a single
2 action will provide substantial benefits to all parties and to the Court. Class Members are readily
3 identifiable from information and records in the possession, custody, or control of Defendants,
4 retailers of Prescription Pet Food, veterinarians, and the Class Members.

5 90. Common questions of law and fact exist as to all members of the Classes, and
6 predominate over any questions solely affecting individual members of each Class. Questions of
7 law and fact common to each of the Classes include the following:

8 a. Whether Defendants may self-impose a "prescription" requirement on
9 products they manufacture, market, and/or sell, notwithstanding that the product is not a drug and
10 has not been subjected to FDA review or clearance as a drug;

11 b. Whether the Prescription Authorization and Defendants' related
12 representations and omissions materially misrepresent that Prescription Pet Food contains some
13 substance medically necessary to health;

14 c. Whether the Prescription Authorization and Defendants' related
15 representations and omissions materially misrepresent that Prescription Pet Food is some sort of
16 drug, medicine, or other controlled ingredient;

17 d. Whether the Prescription Authorization and Defendants' related
18 representations and omissions materially misrepresent that the statements regarding the intended
19 uses and effects of Prescription Pet Food have been evaluated by the FDA;

20 e. Whether the Prescription Authorization and Defendants' related
21 representations and omissions materially misrepresent that Prescription Pet Food requires a
22 prescription per a federal, state, or other governmental body or agency law;

23 f. Whether the Prescription Authorization and Defendants' related
24 representations and omissions materially misrepresent that Prescription Pet Food is so materially
25 different from no-prescription-required pet food that paying a price premium is warranted;

26 g. Whether the Prescription Pet Foods are misbranded;

27 h. Whether Plaintiffs and Class Members are entitled to a declaratory
28 judgment;

1 i. Whether Plaintiffs and Class Members are entitled to equitable relief,
2 including, but not limited to, a preliminary and/or permanent injunction;

3 j. Whether Plaintiffs and Class Members are entitled to restitution and/or
4 disgorgement and the amount of such;

5 k. Whether Plaintiffs and Class Members are entitled to punitive or exemplary
6 damages and the amount of such; and

7 l. Whether Defendants should be required to make restitution, disgorge
8 profits, reimburse losses, pay damages, and/or pay treble damages as a result of the above-
9 described practices.

10 91. Other common questions that predominate over any questions affecting only
11 individual Class Members include:

12 a. Whether Defendants have agreed, combined, or conspired to fix, raise,
13 stabilize, or peg the prices of Prescription Pet Food (Nationwide Direct Purchaser Class);

14 b. Whether Defendants' conspiracy to fix, raise, stabilize, or peg the prices of
15 Prescription Pet Food has caused injury to business or property (Nationwide Direct Purchaser
16 Class);

17 c. The amount of the overcharge and damage paid as a result of Defendants'
18 conspiracy to fix, raise, stabilize, or peg the prices of Prescription Pet Food (Nationwide Direct
19 Purchaser Class);

20 d. Whether Defendants' actions as described above violate Section 1 of the
21 Sherman Act, 15 U.S.C. § 1 (Nationwide Direct Purchaser Class);

22 e. Whether Defendant manufacturers' actions as described above violate the
23 California Unfair Competition Law, California Business & Professions Code §§ 17200, *et seq.*
24 (Royal Canin California Class, Iams California Class, and Hill's California Class);

25 f. Whether Defendant manufacturers' actions as described above violate the
26 California False Advertising Law, California Business & Professions Code §§ 17500, *et seq.*
27 (Royal Canin California Class, Iams California Class, and Hill's California Class); and
28

1 g. Whether Defendant manufacturers' actions as described above violate the
2 California Consumers Legal Remedies Act, California Civil Code §§ 1750, *et seq.* (Royal Canin
3 California Class, Iams California Class, and Hill's California Class).

4 92. Plaintiffs/Class Representatives' claims are typical of the claims of Class Members
5 because Plaintiffs and each member of the Classes purchased Prescription Pet Food, and suffered a
6 monetary loss as a result of that purchase. Further, the factual bases of Defendants' conduct are
7 common to all Plaintiffs in each Class and represent a common thread of misconduct resulting in
8 injury common to all Class Members.

9 93. Plaintiffs/Class Representatives are adequate representatives of the respective
10 Classes because their interests do not conflict with the interests of the Class Members they seek to
11 represent, they have retained competent counsel experienced in prosecuting class actions, and they
12 intend to prosecute this action vigorously. The interests of Class Members will be fairly and
13 adequately protected by Plaintiffs and their counsel.

14 94. Class certification and class-wide litigation and relief are appropriate because a
15 class action is superior to all other available methods for the fair and efficient adjudication of this
16 controversy. Joinder of all members is impracticable. Furthermore, as the damages suffered by
17 the individual members of the Classes may be relatively small, the expense and burden of
18 individual litigation make it impossible for most members of the Classes individually to redress
19 the wrongs done to them. Absent a class action, Class Members' damages will go uncompensated,
20 and Defendants' misconduct will continue without remedy. Class treatment of common questions
21 of law and fact will also be superior to multiple individual actions or piecemeal litigation in that
22 class treatment will conserve the resources of the courts and the litigants, and will promote
23 consistency and efficiency of adjudication.

24 95. Defendants have acted in a uniform manner with respect to the Plaintiffs and Class
25 Members of each Class.

26 96. Class-wide declaratory, equitable, and injunctive relief is appropriate under Rule
27 23(b)(1) and/or (b)(2) because Defendants have acted on grounds that apply generally to the
28 Classes, and inconsistent adjudications with respect to Defendants' liability would establish

1 incompatible standards and substantially impair or impede the ability of Class Members to protect
2 their interests. Class-wide relief assures fair, consistent, and equitable treatment and protection of
3 all Class Members, and uniformity and consistency in Defendants' discharge of their duties to
4 perform corrective action regarding Prescription Pet Food.

5 **CAUSE OF ACTION I**
6 **VIOLATION OF SECTION 1 OF SHERMAN ACT**
7 **(15 U.S.C. § 1)**
8 ***(All Defendants)***

9 97. Plaintiffs/Class Representatives and Class Members hereby re-allege and
10 incorporate by reference the allegations of the preceding paragraphs as if fully set forth herein.

11 98. As set forth hereinabove, during the four years next prior to the filing of this
12 Complaint, Defendants entered into a continuing agreement, combination, and conspiracy in
13 restraint of trade to fix, raise, stabilize, or peg prices of Prescription Pet Food in per se violation of
14 Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1.

15 99. The contract, combination, or conspiracy alleged above has substantial horizontal
16 elements, including agreements between Defendant manufacturers, to limit competition between
17 and among themselves with regard to Prescription Pet Food, even though they otherwise would be
18 competitors in the pet food market, such that application of the per se rule is justified under the
19 facts and circumstances set forth herein.

20 100. Alternatively, the contract, combination, or conspiracy alleged above has resulted
21 in substantial anticompetitive effects in the United States market for pet food, without any
22 countervailing procompetitive benefits, and thereby violates Section 1 under the Rule of Reason,
23 under either full Rule of Reason treatment or Quick Look treatment.

24 101. This contract, combination, or conspiracy has led to anticompetitive effects,
25 including unjustifiably increased prices, and otherwise caused injury to consumers and
26 competition in the relevant market.

27 102. Defendants' contract, combination, agreement, understanding, or concerted action
28 occurred in or affected interstate commerce.

1 103. Defendants' unlawful conduct was through mutual understandings, combinations,
2 or agreements by, between, and among Defendants.

3 104. Defendants' anticompetitive conduct has directly and proximately caused antitrust
4 injury, in the form of higher prices charged to consumers, as set forth above. Plaintiffs/Class
5 Representatives and other consumers will continue to suffer antitrust injury and other damage
6 unless Defendants are enjoined from continuing to engage in the foregoing violations of law.

7 105. Plaintiffs/Class Representatives are entitled to all damages proximately caused by
8 Defendants' anticompetitive conduct, including the unjustified price premium paid by them, and
9 are entitled to three-fold such damages as they show themselves to have sustained and the jury
10 shall find, together with injunctive relief, and their cost of suit, including reasonable attorneys'
11 fees, pursuant to Sections 4 and 16 of the Clayton Antitrust Act, 15 U.S.C. §§ 15, 26.

12 **CAUSE OF ACTION II**
13 **VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW**
14 **(Bus. & Prof. Code §§ 17200, et seq.)**
15 **(Mars and Hill's)**

16 106. Plaintiffs/Class Representatives and Class Members hereby re-allege and
17 incorporate by reference the allegations of the preceding paragraphs as if fully set forth herein.

18 107. Each Defendant manufacturer is subject to the Unfair Competition Law ("UCL"),
19 Business & Professions Code §§ 17200, et seq. The UCL provides, in pertinent part: "Unfair
20 competition shall mean and include unlawful, unfair or fraudulent business practices and unfair,
21 deceptive, untrue or misleading advertising"

22 108. Each Defendant manufacturer violated the "unlawful" prong of the UCL by
23 violating California's Consumers Legal Remedies Act ("CLRA") as described in Cause of Action
24 IV.

25 109. Each Defendant manufacturer also violated the "unlawful" prong of the UCL by
26 violating California's False Advertising Law ("FAL") as described in Cause of Action III.

27 110. Each Defendant manufacturer's conduct, described herein, violated the "unfair"
28 prong of the UCL because each Defendant manufacturer misrepresented through the Prescription

1 Authorization, its advertising and marketing statements, and its failure to include any adequate
2 disclaimer on Prescription Pet Food labels, that consumers purchasing Prescription Pet Food:

- 3 a. are purchasing some sort of drug, medicine, or other controlled
4 ingredient(s);
- 5 b. are meeting a medicinal requirement for their pet's health and well-being;
- 6 c. are purchasing a pet food that has been evaluated by the FDA as a drug;
- 7 d. are purchasing a pet food as to which the representations regarding intended
8 uses and effects have been evaluated by the FDA;
- 9 e. are purchasing a pet food requiring a prescription per a federal, state, or
10 other governmental body or agency; and
- 11 f. are purchasing a pet food for which a particular price premium is warranted.

12 111. Each Defendant manufacturer's conduct, described herein, violated the "fraudulent"
13 prong of the UCL because each Defendant manufacturer misrepresented through the Prescription
14 Authorization, its advertising and marketing statements, and its failure to include any adequate
15 disclaimer on Prescription Pet Food labels, that consumers purchasing Prescription Pet Food:

- 16 a. are purchasing some sort of drug, medicine, or other controlled
17 ingredient(s);
- 18 b. are meeting a medicinal requirement for their pet's health and well-being;
- 19 c. are purchasing a pet food that has been evaluated by the FDA as a drug;
- 20 d. are purchasing a pet food as to which the representations regarding intended
21 uses and effects have been evaluated by the FDA;
- 22 e. are purchasing a pet food requiring a prescription per a federal, state, or
23 other governmental body or agency; and
- 24 f. are purchasing a pet food for which a particular price premium is warranted.

25 112. Plaintiffs/Class Representatives and Class Members suffered lost money or
26 property as a result of each Defendant manufacturer's UCL violations because: (a) they would not
27 have purchased Prescription Pet Food or would not have purchased Prescription Pet Food on the
28

1 same terms if the true facts concerning those products had been known; and (b) they paid a price
2 premium due to the false representations and omissions about the products.

3 **CAUSE OF ACTION III**
4 **VIOLATION OF CALIFORNIA'S FALSE ADVERTISING LAW ("FAL")**
5 **(Bus. & Prof. Code § 17500 *et seq.*)**
6 **(*Mars and Hill's*)**

7 113. Plaintiffs/Class Representatives and Class Members hereby re-allege and
8 incorporate by reference the allegations of the paragraphs above as if fully set forth herein.

9 114. Each Defendant manufacturer violated California Business & Professions Code
10 § 17500 by publicly disseminating misleading and false advertisements through the Prescription
11 Authorization itself, and through advertising and marketing statements, suggesting that consumers
12 purchasing Prescription Pet Food:

- 13 a. are purchasing some sort of drug, medicine, or other controlled
14 ingredient(s);
- 15 b. are meeting a medicinal requirement for their pet's health and well-being;
- 16 c. are purchasing a pet food that has been evaluated by the FDA as a drug;
- 17 d. are purchasing a pet food as to which the representations regarding intended
18 uses and effects have been evaluated by the FDA;
- 19 e. are purchasing a pet food requiring a prescription per a federal, state, or
20 other governmental body or agency; and
- 21 f. are purchasing a pet food for which a price premium is warranted.

22 115. Each Defendant manufacturer's misleading and false advertisements were
23 disseminated to increase sales of Prescription Pet Food.

24 116. Each Defendant manufacturer knew or should have known its false advertisements
25 were untrue or misleading.

26 117. Each Defendant manufacturer publicly disseminated the false advertisements as
27 part of a plan or scheme and with the intent to create a price premium for Prescription Pet Food.

28 118. Plaintiffs/Class Representatives and Class Members have suffered harm as a result
of these violations of the FAL because: (a) they would not have purchased Prescription Pet Food

1 or would not have purchased Prescription Pet Food on the same terms if the true facts concerning
2 the products had been known; and (b) Defendant manufacturers did not conform to Defendant
3 manufacturers' representations and promises.

4 119. Pursuant to Business & Professions Code § 17500, Plaintiffs/Class Representatives
5 and Class Members seek an order of this Court permanently enjoining each Defendant
6 manufacturer from continuing to publicly disseminate misleading and false advertisements as
7 alleged herein. Plaintiffs/Class Representatives and Class Members also seek an order requiring
8 each Defendant manufacturer to: (a) make full restitution for all monies wrongfully obtained; and
9 (b) disgorge all ill-gotten revenues and/or profits.

10 **CAUSE OF ACTION IV**
11 **VIOLATION OF CALIFORNIA'S CONSUMER LEGAL REMEDIES ACT ("CLRA")**
12 **(Civil Code §§ 1750, *et seq.*)**
13 **(*Mars and Hill's*)**

14 120. Plaintiffs/Class Representatives and Class Members hereby re-allege and
15 incorporate by reference the allegations of the paragraphs above as if fully set forth herein.

16 121. CLRA § 1770(a) prohibits, among other things, "[m]isrepresenting the affiliation,
17 connection or association with, or certification by, another," "[r]epresenting that goods or services
18 have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do
19 not have," "[r]epresenting that goods or services are of a particular standard, quality or grade or
20 that goods are of a particular style or model, if they are not," and "[a]dvertising goods or services
21 with intent not to sell them as advertised." Each Defendant manufacturer violated these provisions
22 by misrepresenting through the Prescription Authorization, its advertising and marketing
23 statements, and its failure to include any adequate disclaimer on Prescription Pet Food labels, that
24 consumers purchasing Prescription Pet Food:

- 25 a. are purchasing some sort of drug, medicine, or other controlled
26 ingredient(s);
27 b. are meeting a medicinal requirement for their pet's health and well-being;
28 c. are purchasing a pet food that has been evaluated by the FDA as a drug;

1 d. are purchasing a pet food as to which the representations regarding intended
2 uses and effects have been evaluated by the FDA;

3 e. are purchasing a pet food requiring a prescription per a federal, state, or
4 other governmental body or agency; and

5 f. are purchasing a pet food for which a particular price premium is warranted.

6 122. Plaintiffs/Class Representatives and Class Members suffered lost money or
7 property as a result of these violations because: (a) they would not have purchased Prescription
8 Pet Food or would not have purchased Prescription Pet Food on the same terms if the true facts
9 concerning those products had been known; and (b) they paid a price premium due to the false
10 representations and omissions about the products.

11 123. Prior to the filing of this Complaint, CLRA notice letters were served on Mars and
12 Hill's, which complied in all respects with California Civil Code § 1782(a). Plaintiffs/Class
13 Representatives sent each Defendant manufacturer their letter via certified mail, return receipt
14 requested, advising each Defendant manufacturer that it is in violation of the CLRA and must
15 correct, repair, replace or otherwise rectify the goods alleged to be in violation of § 1770. Each
16 Defendant manufacturer was further advised that in the event that the relief requested has not been
17 provided within thirty (30) days, Plaintiffs would amend this Complaint to include a request for
18 monetary damages, including punitive damages, pursuant to the CLRA.

19 **CAUSE OF ACTION V**
20 **RESTITUTION BASED ON QUASI-CONTRACT/UNJUST ENRICHMENT**
21 **(Civil Code §§ 1750, *et seq.*)**
22 ***(Mars and Hill's)***

23 124. Plaintiffs/Class Representatives and Class Members hereby re-allege and
24 incorporate by reference the allegations of the paragraphs above as if fully set forth herein.

25 125. Plaintiffs/Class Representatives conferred benefits on each Defendant manufacturer
26 by purchasing Prescription Pet Food at a premium price.

27 126. Each Defendant manufacturer has knowledge of such benefits.
28

1 127. Each Defendant manufacturer has been unjustly enriched in retaining the revenues
2 derived from Plaintiffs/Class Representatives and Class Members' purchases of Prescription Pet
3 Food.

4 128. Retention of those moneys under these circumstances is unjust and inequitable
5 because each Defendant manufacturer falsely and misleadingly represented through the
6 Prescription Authorization, its advertising and marketing statements, and its failure to include any
7 adequate disclaimer on Prescription Pet Food labels, that consumers purchasing Prescription Pet
8 Food:

- 9 a. are purchasing some sort of drug, medicine, or other controlled
10 ingredient(s);
11 b. are meeting a medicinal requirement for their pet's health and well-being;
12 c. are purchasing a pet food that has been evaluated by the FDA as a drug;
13 d. are purchasing a pet food as to which the representations regarding intended
14 uses and effects have been evaluated by the FDA;
15 e. are purchasing a pet food requiring a prescription per a federal, state, or
16 other governmental body or agency; and
17 f. are purchasing a pet food for which a particular price premium is warranted.

18 129. These misrepresentations and omissions caused injuries to Plaintiffs/Class
19 Representatives and Class Members because they would not have purchased Prescription Pet
20 Food, or paid a price premium for Prescription Pet Food, had the true facts been known.

21 130. Because each Defendant manufacturer's retention of the non-gratuitous benefits
22 conferred on it by Plaintiffs/Class Representatives and Class Members is unjust and inequitable,
23 Defendant manufacturers ought to pay restitution to Plaintiffs/Class Representatives and Class
24 Members for their unjust enrichment, as ordered by the Court.

25 131. As a direct and proximate result of each Defendant manufacturer's unjust
26 enrichment, Plaintiffs/Class Representatives and Class Members are entitled to restitution or
27 restitutionary disgorgement in an amount to be proven at trial.

28 ///

RELIEF DEMANDED

1
2 WHEREFORE, Plaintiffs/Class Representatives, individually and on behalf of all others
3 similarly situated, request the Court enter judgment against Defendants including:

4 1. An order certifying the Nationwide Direct Purchaser Class, the Royal Canin
5 California Class, the Iams California Class, and the Hill's California Class under Rule 23 of the
6 Federal Rules of Civil Procedure and naming the respective Plaintiffs as representatives of the
7 respective Classes, and Plaintiffs' attorneys as Class Counsel to represent the Class Members;

8 2. An order enjoining Defendants from engaging in further deceptive distribution,
9 marketing, and/or sales practices with respect to Prescription Pet Food;

10 3. A declaration that Defendants are financially responsible for notifying all Class
11 Members about the true nature of Prescription Pet Food;

12 4. An order declaring that Defendants' conduct violates the statutes referenced herein;

13 5. An order finding in favor of Plaintiffs/Class Representatives and the members of
14 the Classes on all Causes of Action asserted herein;

15 6. An order finding in favor of Plaintiffs/Class Representatives and the Classes on all
16 Causes of Action asserted herein;

17 7. A declaration that Defendants must disgorge, for the benefit of Plaintiffs and Class
18 Members, all or part of the ill-gotten profits received from the sale of Prescription Pet Food;

19 8. An award of three-fold damages;

20 9. An award of compensatory, statutory, exemplary, and punitive damages in amounts
21 to be determined by the Court and/or jury;

22 10. An award of prejudgment interest on all amounts awarded;

23 11. An order of restitution and all other forms of equitable monetary relief;

24 12. Injunctive relief as plead or as the Court may deem proper; and

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26 ///

27 ///

28 ///

EXHIBIT A

[Home \(/default.asp\)](#) // [Press Center \(/press_overview.asp\)](#) // [Pet Industry Market Size & Ownership Statistics](#)

Pet Industry Market Size & Ownership Statistics

U.S. Pet Industry Spending Figures & Future Outlook

The following spending statistics are gathered by APPA from various market research sources and are not included in the organization's bi-annual National Pet Owners Survey.

Total U.S. Pet Industry Expenditures

<u>Year</u>	<u>Billions of dollars</u>
2016	\$62.75 Estimated
2015	\$60.28 Actual
2014	\$58.04
2013	\$55.72
2012	\$53.33
2011	\$50.96
2010	\$48.35
2009	\$45.53
2008	\$43.2
2007	\$41.2
2006	\$38.5
2005	\$36.3
2004	\$34.4
2003	\$32.4
2002	\$29.6
2001	\$28.5
1998	\$23
1996	\$21
1994	\$17

Actual Sales within the U.S. Market in 2015

In 2015, \$60.28 billion was spent on our pets in the U.S.

Breakdown:

Food	\$23.05 billion
Supplies/OTC Medicine	\$14.28 billion

Vet Care	\$15.42 billion
Live animal purchases	\$2.12 billion
Pet Services: grooming & boarding	\$5.41 billion

Estimated 2016 Sales within the U.S. Market

For 2016, it *estimated* that \$62.75 billion will be spent on our pets in the U.S.

Estimated Breakdown:

Food	\$24.01 billion
Supplies/OTC Medicine	\$14.98 billion
Vet Care	\$15.92 billion
Live animal purchases	\$2.11 billion
Other Services	\$5.73 billion

Data sources and notes

1. Food total is based on PFI research consultant Davenport Co, Packaged Facts Pet Food in the U.S. 2013-2018, and petfoodindustry.com 2015 Industry Report, and Euromonitor International Pet Care in the US.
2. Supplies based on APPA historical, BCC Research-The Pet Industry, Fountain Agricounsel 2014-2015 Situation Analysis, Pet Product News, Packaged Facts Pet Supplies in the US 2015, IBISWorld Industry Report Pet Stores in the US and Cleveland Research 2015 Forecast.
3. Veterinary care includes routine vet care and is based on AVMA, Newsweek, Brakke Consulting, Bain & Co, Fountain Agricounsel 2015 Situation Analysis Report and Packaged Facts Pet Supplies in the US 2015.
4. Live Animal purchases based on APPA, AVMA, Barron's Research, Fountain Agricounsel, Packaged Facts Pet Population and Ownership Trends and Euromonitor estimates.
5. Other Services based on Packaged Facts, LA Times, APPA State of the Industry Report, Newsweek, Dillon Media Trends Report, IBISWorld and Smallbiztrends.com data.
6. Other Services include grooming, boarding, training, pet sitting, pet exercise, miscellaneous.
7. Pet insurance figures are included in Veterinary Care.

2015-2016 APPA National Pet Owners Survey Statistics: Pet Ownership & Annual Expenses

- According to the 2015-2016 APPA National Pet Owners Survey (/pubs_survey.asp), 65% of U.S. households own a pet, which equates to 79.7 millions homes
- In 1988, the first year the survey was conducted, 56% of U.S. households owned a pet.

Breakdown of pet ownership in the U.S. according to the 2015-2016 APPA National Pet Owners Survey (/pubs_survey.asp)

Number of U.S. Households that Own a Pet (millions)

Bird	6.1
Cat	42.9
Dog	54.4
Horse	2.5
Freshwater Fish	12.3
Saltwater Fish	1.3
Reptile	4.9
Small Animal	5.4

Total Number of Pets Owned in the U.S. (millions)

Bird	14.3
Cat	85.8
Dog	77.8
Horse	7.5
Freshwater Fish	95.5
Saltwater Fish	9.5
Reptile	9.3
Small Animal	12.4

Basic Annual Expenses

The section serves as a benchmark and the dollar amounts for the categories listed should not be added to report total spending in the prior 12 months. It reports an approximate dollar amount based on consumer recollection of their spending in the prior 12 months. The list is not inclusive of all items possibly purchased, as some items fall into “other” expenses and are not reported here. As such, the dollar amounts should not be added to report total spending in the prior 12 months.

According to the 2015-2016 APPA National Pet Owners Survey (http://www.americanpetproducts.org/pubs_survey.asp), some of the basic annual expenses for dog and cat owners in dollars include:

	Dogs	Cats
Surgical Vet Visits	\$551	\$398
Routine Vet	\$235	\$196
Food	\$269	\$246
Food Treats	\$61	\$51
Kennel Boarding	\$333	\$130
Vitamins	\$62	\$33
Groomer/Grooming Aids	\$83	\$43
Toys	\$47	\$28

****Note:** APPA does not ask Survey Participants how much in total they spend on their dog or cats annually. The expenses listed above are not all inclusive and each category was asked separately of the survey participant.



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Pets by the Numbers

U.S. Pet Ownership, Community Cat and Shelter Population Estimates



If just one of every five Americans wanting to add a cat or dog to their family in the next year adopted from a shelter or rescue, not one single healthy, treatable cat or dog would lose his or her life in a shelter! Photo by Michelle Riley/The HSUS

Understanding the Data

Obtaining accurate statistical data about pets in the United States isn't easy. Most of the information is based on estimates derived from surveys, and the various survey-takers don't always agree. Data reflecting shelter/rescue animal populations is spotty due to a lack of reporting requirements, which leaders in animal welfare are aiming to address with the Shelter Animals Count project.

There are two main sources of pet demographics in the United States: the biennial *APPA National Pet Owners Survey* by the American Pet Products Association, and the *U.S.*

Pet Ownership & Demographics Sourcebook by the American Veterinary Medical Association (AVMA) which is published every five years. Together these surveys provide data about trends in pet ownership and produce a reasonably accurate estimate of the total number of dogs and cats.

The Numbers

U.S. Pet Ownership Estimates

U.S. PET OWNERSHIP ESTIMATES

FACT	2012 AVMA SOURCEBOOK	2015-2016 APPA SURVEY
Number of households with a pet	66.5 million (year-end 2011)	79.7 million
Percentage of households with a pet	56% (year-end 2011)	65%
Pet-owning households with more than 1 pet	62.2%	42%
Estimated number of pet dogs and cats	144.1 million	163.6 million
Percentage of pet-owners who consider their pets to be family members	63.2%	
Percentage of pet-owners who consider their pets to be pets or companions	35.8%	
Percentage of pet-owners who consider their pets to be property	1%	
Average amount spent on veterinary care per year per pet (cat or dog)	\$158.50	\$1,288.50

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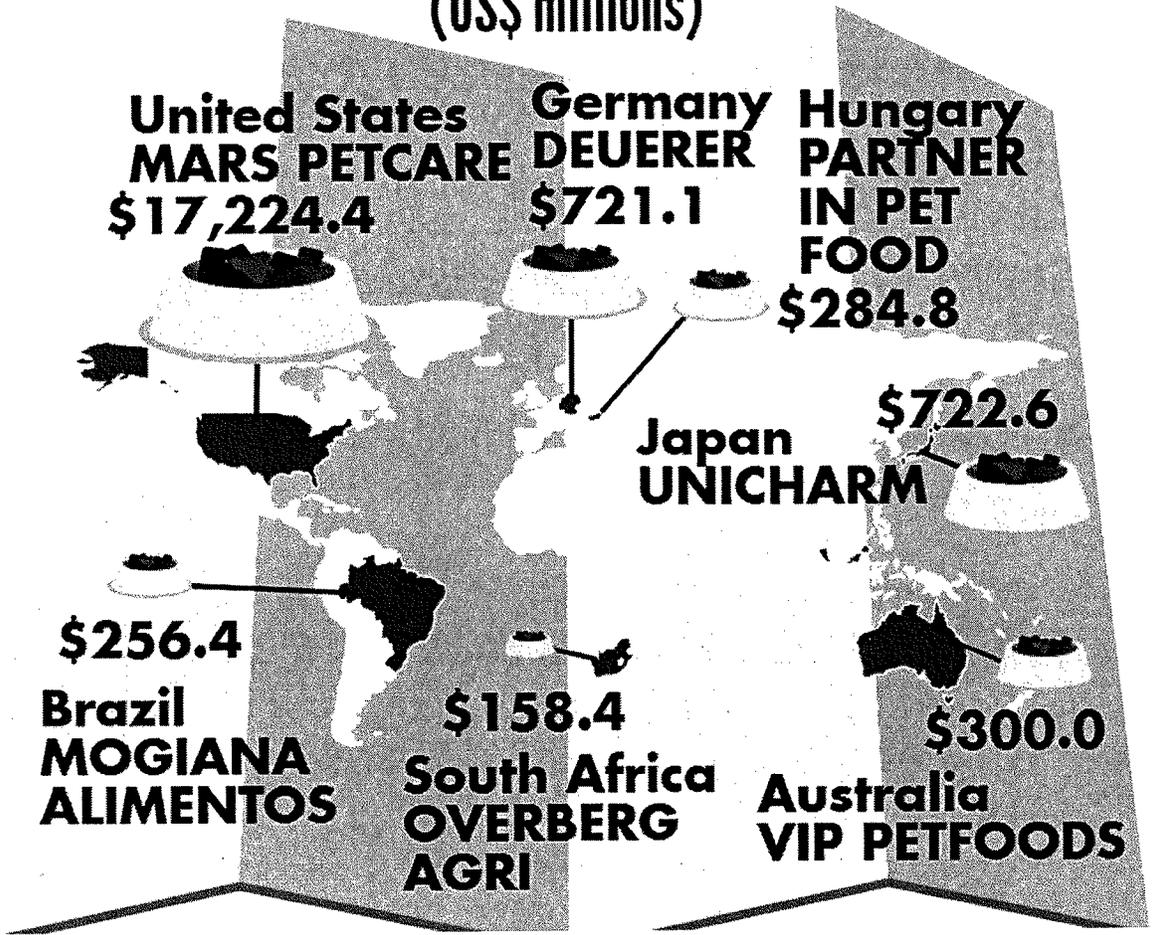
BY ALYSSA CONWAY ON JUNE 13, 2016

INFOGRAPHIC: World's top pet food companies in 2015

The global pet food market was profitable in 2015, with many pet food companies holding their spots as top earners and mergers and acquisitions boosting profitability for others.

WORLD'S TOP **PET FOOD COMPANIES** **IN 2015**

.....
Top pet food company in each region by 2015 annual revenue (US\$ millions)



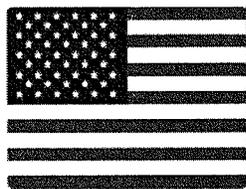
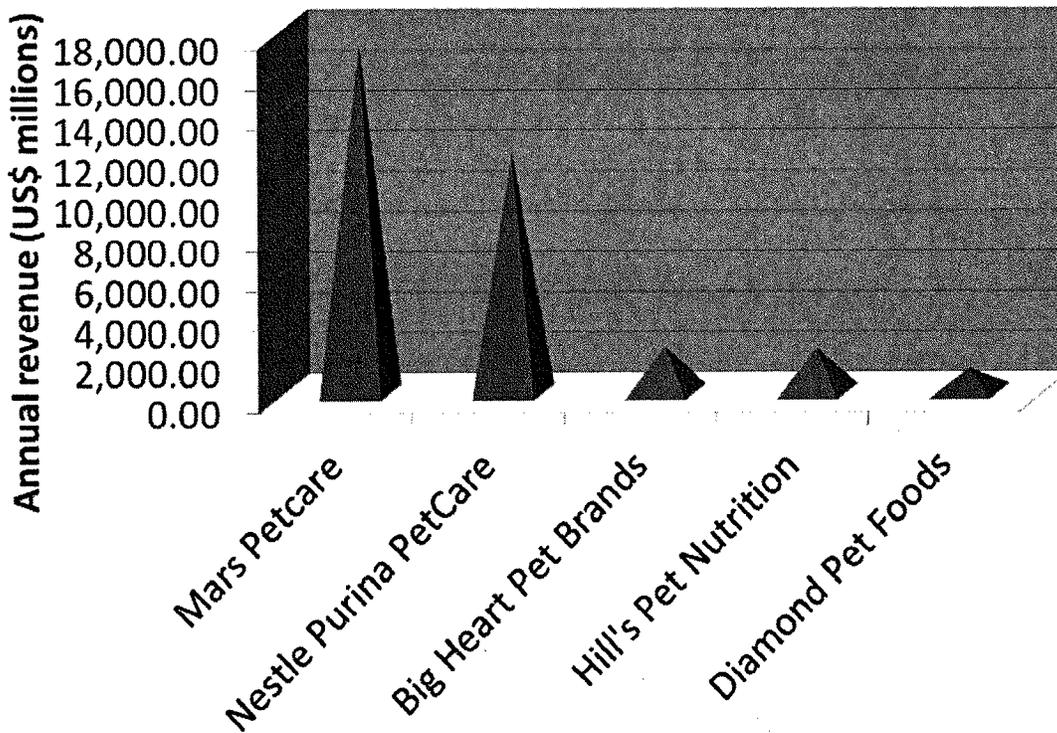
The top 40 pet food companies drew more than



US\$45.989 billion in annual revenue in 2015



Top 5 pet food companies of 2015



12 of the top 20 pet food producers in 2015 are headquartered in the United States

SOURCE: PETFOODINDUSTRY.COM TOP COMPANIES DATABASE

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Petfood Industry's annual Top Pet Food Companies issue highlights the shifts within the world's pet food industry that have taken place over the past year.

As a whole, the world's top 40 pet food companies that made the list earned nearly US\$46 billion in annual revenue in 2015. Once again, the major earners—Mars Petcare and Nestle Purina PetCare—ranked No. 1 and No. 2 with US\$17.224 billion and US\$11.917 billion, respectively, in 2015 annual revenue.

Like Mars and Nestle, a majority of the top companies are based in the US. While one of the major US players from 2014, P&G Pet Care, sold its pet food business and exited the market, another US company now ranks on the list as a result. After acquiring P&G's European pet food businesses at the end of 2014, including the Iams and Eukanuba brands, Spectrum Brands/United Pet Group brought in US\$800 million in annual revenue in 2015 to sit at No. 7 on the Top Companies list.

Newly ranking in the Top 10 for 2015 was Japan-based Unicharm, which drew US\$722.6 million in annual revenue in 2015—notably higher than its 2013 revenue of US\$268.8. Unicharm's significant growth over the past two years highlights the growth in Asian pet food market as a whole, which, according to Euromonitor International data, ranks among the highest rate around the world for 2015.

Log in or subscribe to read the entire May 2016 *Petfood Industry* digital edition, with analysis and profiles on each of the world's top 40 pet food manufacturers.

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Market Research Statistics: U.S. Veterinarians 2015

	Total (No.) ¹	Male	Female	Unknown
Total	105,358	44,204	60,988	166

U.S. Veterinary Positions (among employed veterinarians)

Definitions of categories below

	Total as of December 31, 2015 ^{1,2} No.	Percent of Total	Male %	Female %
Private Clinical Practice				
Food animal exclusive	1,233	1.8%	80.0%	20.0%
Food animal predominant	3,371	5.0%	78.0%	22.0%
Mixed animal	4,177	6.3%	60.5%	39.5%
Companion animal predominant	6,080	9.1%	54.5%	45.5%
Companion animal exclusive	43,851	65.7%	39.9%	60.1%
Equine	3,874	5.8%	49.9%	50.1%
Other	266	0.4%	39.5%	60.5%
Species Unspecified	3,907	5.9%	22.8%	77.2%
Total Private Practice	66,759	100%	44.8%	55.2%
Public & Corporate Employment				
College or university	6,596	41.6%	44.8%	55.2%
Federal government	1,808	11.45%	56.7%	43.3%
State or local government	1,054	6.6%	52.0%	48.0%
Uniformed services	772	4.9%	48.8%	51.2%
Industry	3,324	21.0%	56.9%	43.1%
Other Public & Corporate	2,300	14.5%	34.7%	65.3%
Total Public & Corporate	15,854	100%	47.8%	52.2%
Employment Unknown	27,015			
Not Listed Above	1,778			
Total # of Positions held by U.S. Veterinarians	111,406			

¹ Includes active AVMA members (Regular, Recent Graduates, and Educational) and Non-members (Excludes non-members born prior to 1944 and non-members who received their veterinary degree prior to 1970)

² Veterinarians may hold more than one position.

³ Data referenced from the AVMA Report on Veterinary Compensation, 2015 Edition

Updated 3/16.

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The species categories listed under Private Clinical Practice can be defined by the following calculations.

Species categories

- Food animal exclusive: Sum of (Bovine, Porcine, Ovine/Caprine, Camelid, Cervid and Poultry) is at least 90% of the contact.
- Food animal predominant: Sum of (Bovine, Porcine, Ovine/Caprine, Camelid, Cervid and Poultry) is at least 50% of the contact.
- Mixed animal: Varied species with at least 25% from companion animal and 25% from either food animal or equine.
- Companion animal predominant: Sum of (Canine, Feline, Avian (non-poultry) and Exotics) is at least 50% of the contact.
- Companion animal exclusive: Sum of (Canine, Feline, Avian (non-poultry) and Exotics) is at least 90% of the contact.
- Equine: Combination of equine predominant and exclusive where there's at least 50% contact with equines.

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Hill's Prescription Diet	
Canine	a/d Canine/Feline-Canned
	b/d Canine-Dry
	c/d Multicare Canine Chicken & Vegetable Stew-Canned
	c/d Multicare Canine-Canned
	c/d Multicare Canine-Dry
	Canine Metabolic Advanced Weight Solution Treats
	Canine Mobility Treats
	d/d Canine Duck Formula-Canned
	d/d Canine Potato & Duck Formula-Dry
	d/d Canine Potato & Salmon Formula-Dry
	d/d Canine Potato & Venison Formula-Dry
	d/d Canine Salmon Formula-Canned
	d/d Canine Venison Formula-Canned
	Derm Defense Canine Chicken & Vegetable Stew-Canned
	Derm Defense Canine-Dry
	g/d Canine-Canned
	g/d Canine-Dry
	h/d Canine-Canned
	h/d Canine-Dry
	Hypo-Treats
	i/d Canine Chicken & Vegetable Stew-Canned
	i/d Canine-Canned
	i/d Canine-Dry
	i/d Low Fat Canine Rice, Vegetable & Chicken Stew-Canned
	i/d Low Fat Canine-Canned
	i/d Low Fat Canine-Dry
	i/d Sensitive Canine-Dry
	i/d Stress Canine Rice, Vegetable & Chicken Stew-Canned
	i/d Stress Canine-Dry
	j/d Canine Small Bites-Dry
	j/d Canine-Canned
	j/d Canine-Dry
	k/d Canine Beef & Vegetable Stew-Canned
	k/d Canine Chicken & Vegetable Stew-Canned
	k/d Canine with Lamb-Canned
	k/d Canine with Lamb-Dry
	k/d Canine-Canned
	k/d Canine-Dry
	l/d Canine-Canned
	l/d Canine-Dry
	Metabolic + Mobility Canine Vegetable & Tuna Stew-Canned
	Metabolic + Mobility Canine-Dry
	Metabolic Canine Lamb Meal & Rice Formula-Dry
	Metabolic Canine Vegetable & Beef Stew-Canned
	Metabolic Canine Vegetable & Chicken Stew-Canned
	Metabolic Canine-Canned
	Metabolic Canine-Dry
n/d Canine-Canned	
r/d Canine-Canned	
r/d Canine-Dry	
s/d Canine-Canned	
t/d Canine Small Bites-Dry	
t/d Canine-Dry	
u/d Canine-Canned	
u/d Canine-Dry	

Feline

w/d Canine Vegetable & Chicken Stew-Canned
w/d Canine-Canned
w/d Canine-Dry
z/d Canine Small Bites-Dry
z/d Canine-Canned
z/d Canine-Dry
Feline Metabolic Advanced Weight Solution Treats
Hypo-Treats
Metabolic + Urinary Feline-Dry
Metabolic + Urinary Feline Vegetable & Chicken Stew-Canned
Metabolic + Urinary Feline Vegetable & Tuna Stew-Canned
Metabolic + Urinary Stress Feline-Dry
Metabolic Feline-Canned
Metabolic Feline-Dry
Metabolic Feline Vegetable & Chicken Stew-Canned
Metabolic Feline Vegetable & Tuna Stew-Canned
Metabolic Feline with Ocean Fish-Dry
c/d Multicare Feline Chicken & Vegetable Stew-Canned
c/d Multicare Feline Stress-Dry
c/d Multicare Feline Vegetable, Tuna & Rice Stew-Canned
c/d Multicare Feline with Chicken-Canned
c/d Multicare Feline with Chicken-Dry
c/d Multicare Feline with Ocean Fish-Canned
c/d Multicare Feline with Ocean Fish-Dry
c/d Multicare Stress Feline Chicken & Vegetable Stew-Canned
d/d Feline Duck & Green Pea Formula-Dry
d/d Feline Duck Formula-Canned
d/d Feline Venison & Green Pea Formula-Dry
d/d Feline Venison Formula-Canned
g/d Feline-Canned
g/d Feline-Dry
i/d Feline-Canned
i/d Feline-Dry
i/d Feline Chicken & Vegetable Stew-Canned
j/d Feline-Canned
j/d Feline-Dry
k/d Feline-Dry
k/d Feline Chicken & Vegetable Stew-Canned
k/d Feline Vegetable & Tuna Stew-Canned
k/d Feline with Chicken-Canned
k/d Feline with Ocean Fish-Canned
k/d Feline with Ocean Fish-Dry
l/d Feline-Canned
l/d Feline-Dry
m/d Feline-Canned
m/d Feline-Dry
r/d Feline-Canned
r/d Feline-Dry
s/d Feline-Canned
s/d Feline-Dry
t/d Feline-Dry
w/d Feline-Canned
w/d Feline-Dry
y/d Feline-Canned
y/d Feline-Dry

	z/d Feline-Canned	
	z/d Feline-Dry	
Royal Canin Veterinary Diet		
Canine	Canine Gastrointestinal Fiber Response-Dry	
	Canine Gastrointestinal High Energy-Canned	
	Canine Gastrointestinal High Energy-Dry	
	Canine Gastrointestinal Low Fat-Canned	
	Canine Gastrointestinal Low Fat-Dry	
	Canine Gastrointestinal Moderate Calorie-Dry	
	Canine Gastrointestinal Puppy-Dry	
	Canine Hydrolyzed Protein Adult HP-Dry	
	Canine Hydrolyzed Protein -Canned	
	Canine Hydrolyzed Protein Moderate Calorie-Dry	
	Canine Hydrolyzed Protein PS-Dry	
	Canine Hydrolyzed Protein Small Breed-Dry	
	Canine Satiety Support Small Dog-Dry	
	Canine Satiety Support-Canned	
	Canine Satiety Support-Dry	
	Canine Selected Protein Adult PD-Canned	
	Canine Selected Protein Adult PD-Dry	
	Canine Selected Protein Adult PR-Canned	
	Canine Selected Protein Adult PR-Dry	
	Canine Selected Protein Adult PV-Canned	
	Canine Selected Protein Adult PV-Dry	
	Canine Selected Protein Adult PW Moderate Calorie-Dry	
	Canine Selected Protein Adult PW-Canned	
	Canine Ultamino-Dry	
	Canine Urinary SO Moderate Calorie-Canned	
	Canine Urinary SO Moderate Calorie-Dry	
	Canine Urinary SO Small Dog-Dry	
	Canine Urinary SO-Canned	
	Canine Urinary SO-Dry	
	Canine Urinary UC Low Purine-Dry	
	Canine Weight Control Large Dog-Dry	
	Canine Weight Control Small Dog-Dry	
	Canine Weight Control-Canned	
	Canine Weight Control-Dry	
	Feline	Feline Calorie Control CC High Fiber-Canned
		Feline Calorie Control-Canned
		Feline Calorie Control-Dry
		Feline Gastrointestinal Fiber Response-Dry
		Feline Gastrointestinal High Energy-Canned
		Feline Gastrointestinal High Energy-Dry
Feline Gastrointestinal Moderate Calorie-Canned		
Feline Gastrointestinal Moderate Calorie-Dry		
Feline Hydrolyzed Protein Adult HP-Dry		
Feline Mature Consult Moderate Calorie-Dry		
Feline Satiety Support-Dry		
Feline Selected Protein Adult PD-Canned		
Feline Selected Protein Adult PD-Dry		
Feline Selected Protein Adult PR-Canned		
Feline Selected Protein Adult PR-Dry		
Feline Selected Protein Adult PV-Canned		
Feline Selected Protein Adult PV-Dry		

	Feline Urinary SO Moderate Calorie-Canned
	Feline Urinary SO Moderate Calorie-Dry
	Feline Urinary SO Olfactory Attraction-Dry
	Feline Urinary SO-Canned
	Feline Urinary SO-Dry
	Feline Weight Control-Canned
	Feline Weight Control-Dry
Purina Pro Plan Veterinary Diets	
Canine	DCO Dual Fiber Control Canine-Dry
	Dental Chewz
	DH Dental Health Canine-Dry
	DH Dental Health Small Bites Canine-Dry
	DRM Dermatological Management Canine-Dry
	EN Gastroenteric Canine-Canned
	EN Gastroenteric Canine-Dry
	EN Naturals Gastroenteric Canine-Canned
	EN Naturals Gastroenteric Canine-Dry
	Fortiflora Canine
	Gentle Snackers
	HA Hydrolyzed Canine-Dry
	HA Hydrolyzed Chicken Flavor Canine-Dry
	JM Joint Mobility Canine-Dry
	Lite Snackers
	NF Kidney Function Canine-Canned
	NF Kidney Function Canine-Dry
	OM Overweight Management Canine-Canned
	OM Overweight Management Canine-Dry
	OM Select Blend Overweight Management Canine-Dry
	UR Urinary OX/ST Canine-Canned
	Feline
DM Dietetic Management Feline-Canned	
DM Dietetic Management Feline-Dry	
DM Savory Selects Dietetic Management Feline-Canned	
EN Gastroenteric Feline-Canned	
EN Gastroenteric Feline-Dry	
EN Naturals Gastroenteric Feline-Canned	
EN Naturals Gastroenteric Feline-Dry	
HA Hydrolyzed Feline-Dry	
NF Kidney Function Feline-Canned	
NF Kidney Function Feline-Dry	
OM Overweight Management Feline-Canned	
OM Overweight Management Feline-Dry	
OM Savory Selects Overweight Management Feline-Canned	
UR Urinary ST/OX Feline-Canned	
UR Urinary ST/OX Feline-Dry	
UR Urinary ST/OX Salmon Flavor Feline-Canned	
UR Urinary ST/OX Turkey & Giblits Flavor Feline-Canned	
IAMS Veterinary Formula	
Canine	Glucose and Weight Control Plus Optimum Weight Control Canine-Dry
	Intestinal Low-Residue Canine-Canned
	Intestinal Plus Low-Residue Adult Canine-Dry
	Intestinal Plus Low-Residue Puppy Canine-Dry

Feline	Joint Plus Joint Canine-Dry
	Maximum Calorie Plus Canine-Canned
	Renal Plus Canine-Dry
	Skin & Coat Plus Response FP Canine-Dry
	Skin & Coat Plus Response KO Canine-Dry
	Skin & Coat Response FP Canine-Canned
	Weight Loss Rewards Plus Restricted-Calorie Rewards Canine
	Weight Loss/Mobility Plus Restricted-Calorie Canine-Dry
	Glucose and Weight Control Plus Optimum Weight Control Feline-Dry
	Intestinal Low Residue Feline-Dry
	Intestinal Plus Low-Residue Feline-Canned
	Maximum Calorie Canine and Feline-Canned
	Renal Plus Feline-Canned
	Skin and Coat Plus Response LB Feline-Canned
	Urinary O-Moderate PH/O Feline-Canned
	Urinary-O Plus Moderate PH/O Feline-Dry
	Urinary-S Low PH/S Feline-Canned
	Urinary-S Plus Low PH/S Feline-Dry
	Weight Loss Restricted-Calorie Feline-Canned
Weight Loss/Mobility Plus Restricted-Calorie Feline-Dry	

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LEADER

Colgate Gives Doctors Treats For Plugging Its Food Brands

By TARA PARKER-POPE Staff Reporter of The Wall Street Journal

Updated Nov. 3, 1997 9:06 a.m. ET

NEW YORK -- Shopping at a pet store here, Meredith Kane grabs a 4-pound bag of Hill's Science Diet. At \$9, it is nearly double the price of cat food sold in supermarkets. But Ms. Kane is unswerving in her devotion to this "designer" brand for her cats, Cecily, Oscar, Kit Kat and A.J.

Why?

"My vet recommends it," she says.

Every year, millions of people spend a total of \$9.4 billion on pet food -- and many, like Ms. Kane, choose brands solely on a veterinarian's recommendation. Over examining tables across the country, more pet doctors lately are trashing trusted brand names like Purina and Kal-Kan, calling them "junk food," and directing people to shell out an extra \$20 or so for a month's supply of super-premium "high science" foods.

The biggest beneficiaries: Hill's Science Diet lines, made by toothpaste giant Colgate-Palmolive Co., and Eukanuba and Iams brands from Iams Co. of Dayton, Ohio. Sold only through pet stores and veterinary clinics, the designer brands pack more calories per bite and promise higher-quality ingredients based on "pioneering research in animal nutrition" tailored to a pet's "life stage," or age.

The result: Vet suggestions ringing in their ears, many pet owners have switched brands -- and the life-stage category has amassed a Doberman-sized \$2 billion chunk of the market.

But few pet owners know just how far premium-market-leader Hill's has gone to sew up the vet endorsements.

'Vets Trust Them'

Borrowing a page from pharmaceuticals companies, which routinely woo doctors to prescribe their drugs, Hill's has spent a generation cultivating its professional following. It spends hundreds of thousands of dollars a year funding university research and nutrition courses at every one of the 27 U.S. veterinary colleges. Once in practice, vets who sell Science Diet and other premium foods directly from their offices pocket profits of as much as 40%.

"Vets trust them," says Jana Norris, a fresh graduate of the School of Veterinary Medicine at the University of California, Davis. While she was in school, a Hill's program allowed the struggling student to pay just \$3 a bag for a special prescription brand for her cat, Buffalo Jean. A bag normally runs about \$25. She also received a small stipend, courtesy of the Hill's program, to study orthopedic surgery with a Los Angeles vet. "Hill's was just always around," she adds.

A little too much, perhaps, for makers of supermarket brands. During the past five years, Hill's sales have surged more than 20%, and now make up an 8% share of the market -- half that of No. 1 Ralston Purina Co., according to Davenport & Co. in Richmond, Va. For the same period, sales at pet-food giant Ralston grew 11% but its market share fell one percentage point; sales at Mars Inc.'s Kal-Kan unit tumbled 28% and its share slipped three percentage points.

Nabbing Tabby Early

Hill's marketing strategy is especially potent since pets are among the world's most loyal consumers. Nabbing Tabby early is critical: Once a pet takes to a particular brand, a later switch can sometimes cause gastrointestinal troubles; and because a lot of felines are finicky about the look of their vittles, many brands come in distinct shapes, like X's and triangles. Since almost everyone asks their vets what to start feeding a new pet, Hill's cleverly has managed to steer billions its way with that all-important early recommendation.

By chasing after the nation's 126 million cats and dogs through the backdoor of vet offices, Hill's has emerged as a crown jewel at Colgate. Hill's sales -- which last year were nearly \$900 million, up from \$40 million 15 years ago -- reflect the power of word-of-mouth marketing. While some competitors spent between \$40 million and \$90 million each to advertise last year, according to Davenport, Hill's paid \$1.9 million. Chicken feed.

Part of the Family

"The bulk of our expenditure goes to the veterinary community," says John Steel, who

just retired as Colgate's senior vice president of global marketing and sales. The company won't reveal its marketing and promotions budget. He adds: "It's just like taking drugs: You go to the doctor and he prescribes something for you and you don't much question what the doctor says. It's the same with animals." Pet-food marketers also say the rise of high-science vittles has to do with American consumers' obsession with their own health. "People think of pets as an extension of the family," says Robert C. Wheeler, Hill's chief executive.

But the reliance on vet endorsements has its critics. "Consumers think they're getting a better product because veterinarians are recommending it," says Ann Martin, author of a new book, "Foods Pets Die For." She notes that many pet doctors are "brainwashed into thinking they have to recommend these commercial foods," having been so heavily exposed to them in vet schools.

Adds Francis Kallfelz, professor of nutrition at Cornell University's School of Veterinary Medicine in Ithaca, N.Y., "I've never seen any research to prove animals fed premium products all their lives have fared better than animals fed standard products." More definitive research would require "a lot of animals and a lot of time," he says, and it is too early to say there is "one best pet food." Despite that, he feeds his golden retriever Hill's Prescription Diet.

Science and Sales

Pet-food marketers insist it is science, not salesmanship, that ultimately sways many of the estimated 36,000 small-animal veterinarians in the U.S.

At the Hill's research center in Topeka, Kan., scientists proudly point to Cocoa and Brandy, two 18-month-old Labrador retrievers. Since she was a pup, Cocoa has munched only Hill's products, while Brandy ate a Brand X food that Hill's won't name. Brandy is fat and has a dull coat. Cocoa is bright-eyed and slim, with a lustrous coat. "The products do what we say they do," Mr. Wheeler says. "We're not selling dog food. We're selling nutrition."

Makers of supermarket pet foods disagree. Ralston Purina, which now sells two premium lines and is reaching out more to veterinarians, says even its lower-priced foods such as Dog Chow and Puppy Chow provide the same basic nutrients as the super-premium brands. "What you're hearing from veterinarians might be colored somewhat by the products they have for sale," says Larry McDaniel, a vet himself, and Ralston's director of veterinary marketing.

But Hill's has a long history with the veterinary community. Hill's Pet Nutrition was founded in 1948 by Kansas veterinarian Mark Morris, who, in his own kitchen, cooked

up a special diet for treating kidney problems in dogs; 20 years later the company introduced its Science Diet brand, touted as a healthier alternative than the table scraps commonly used or low-priced foods sold in supermarkets.

The company -- which never was more than a niche player in pet food and began to diversify into other pet products, such as flea shampoos and sprays -- was acquired by Colgate in 1976, when Hill's was part of Houston-based Riviana Foods. Several years later when Colgate, of New York, decided to shed all noncore business and put Hill's on the block, a senior executive named Reuben Mark, who would later become Colgate's chairman, argued to keep the fledgling company.

"I was struck by the similarity of our world-wide toothpaste business, with the endorsement of the dentists being so important," Mr. Mark says. "I knew if we did the same thing with Hill's, it could be an enormous global brand."

Marketing Coup

So, similar to Colgate's spadework in dental schools, Hill's now funds a nutrition professorship in nearly half of the nation's vet schools. Hill's employees wrote a widely used textbook on small-animal nutrition that is distributed for free to students. Hill's also sends practicing veterinarians to seminars on wringing more profit from clinics and offers the only formal nutrition-certification program for clinic technicians. In a savvy marketing coup now being copied by other pet-food companies, Hill's each year donates tons of free food for the pets of cash-strapped veterinary students.

Hill's also beefed up its sales force, which has grown to more than 500 people from just 16 in the early 1980s, including many who are vets. Outside universities, Hill's is believed to be the country's single largest employer of veterinarians.

One is Tony Rumschlag, a territory manager for Hill's in Indianapolis. Last month, he arrived at the Post Pet Hospital armed with framed posters to hang on walls, Post-It notes for the reception desk and free samples of Hill's dog treats for the clientele.

Weight Watchers

"Dr. Tony" headed for Exam Room Three, where he met with hospital veterinarian Scot Harbin to talk about recommending Hill's diet foods for the fat cats and pudgy dogs that visit the clinic. Today, Hill's is launching a special two-month promotion to pay the clinic \$3 per animal it puts on a diet. "We're offering a bounty to get pets on a weight-management program," Dr. Rumschlag says.

Dr. Harbin likes the idea, and sets a goal of putting one dog and one cat on a diet each day. The money raised might be used to host a pizza party or even dinner at a fancy

restaurant for the staff, he says.

Later, Dr. Harbin concedes that for years Hill's "sort of had a lock on the veterinary market." But now, he says, competition has increased. "At 12:30, the Eukanuba rep is coming in to give her spiel," he says.

Dr. Rumschlag moves on to the Broad Ripple Animal Clinic, where he hands over 200 custom-printed coupons for pet owners to receive a discount on Hill's food. He also pledges about \$1,200 worth of free puppy and kitten food, about 175 bags, to dole out to new pet owners who visit. Not only will the perquisites help the clinic sell more food, but the coupons could help get pet owners back into the clinic for a checkup, he figures.

David Brunner, who owns the hospital, says the marketing push sometimes makes him uneasy and adds that he is careful to tell clients they can always find the same foods at the pet store. "I don't want to be perceived as a food salesman," he says. "We don't want it to enter clients' minds that 'Oh, you're just trying to sell me dog food.' "

Junk-Food Diet

Yet he and other vets say they are convinced premium foods are far better than cheaper brands. One doctor compared using cheaper supermarket pet foods to feeding a child potato chips and pizza every day. Dr. Kallfelz of Cornell says the basic ingredients in most pet foods are the same, but the difference lies in the amount, quality and concentration of ingredients. In general, he says, standard foods have a higher concentration of vegetable proteins, while premium foods have a higher concentration of animal proteins. Premium foods are generally the same from bag to bag, while the formulation of standard foods can change, depending on market prices for ingredients.

But Dr. Brunner says his trust in Hill's products stems mainly from the success he has had in treating animals with urinary-tract infections, kidney disease and other problems with the specially blended Hill's Prescription Diet foods. The diets can only be prescribed by veterinarians and are more than twice the price of supermarket foods.

Other pet-food makers that have launched their own premium brands, including Purina's Pro-Plan and Mars's Waltham brand, have also tailored their products to tempt vets. Ralston Purina, for instance, offers 13 "therapeutic" diets, which can only be prescribed by vets, to compete with Hill's popular Prescription Diet brand. The company also now has free food programs at a handful of U.S. veterinary colleges, and this year "significantly increased" its veterinary-marketing budget to provide coupons for vet students to receive big discounts on Purina foods.

To compete with Hill's stature in vet schools, Purina last year announced a \$550,000 endowment for a professorship in small-animal nutrition at the University of Missouri-

Columbia College of Veterinary Medicine in Columbia, Mo. The company also provided a \$175,000 grant to the American College of Veterinary Nutrition to develop a "noncommercial" nutrition curriculum for all vet schools to follow.

'Share of Mind'

"We feel strongly if the playing field is leveled in the veterinary colleges, it will go a long way toward unbiased education, and it will only benefit us," says Purina's Dr. McDaniel. "We feel we're making significant inroads into 'share of mind' of the veterinarian."

Not to leave anything to chance, the company is hoping to grab a share of consumers' minds. In new ads for a blend of Purina One, a dog visiting a neighbor's house prefers the Purina One food served up there. The reason? The main ingredient is lamb, the ad says, tastier than the corn in that "designer dog food."

For its part, Mars has hired a public-relations firm to tout its Waltham pet-nutrition-research center in England, and is running ads saying its foods are "developed by vets" at the research facility. Last year, Mars spent \$50 million on advertising, a 50% jump from 1995, according to Davenport.

The rivals are clearly nipping on Hill's heels. New York vet Harold Zweighaft says a sales call from a Purina representative persuaded him to start stocking Purina food along with Hill's. "Now I have as much Purina as I do Hill's," he says. When New York interior designer Christiane Lemieux got her frisky Labrador pup Jake six months ago, she was all too happy to snap up some Eukanuba Lamb & Rice, on her vet's recommendation. "It has coat enhancers," she says, stroking Jake's smooth amber fur. "My vet says it's the highest-quality brand."

EXHIBIT G

Leaven / facile à ouvrir / Mel de abel

ROYAL CANIN

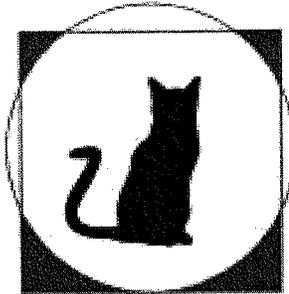


ROYAL CANIN

**CALM
CALME**



**FELINE
FÉLINE**



**VETERINARY DIET
FORMULE VÉTÉRINAIRE**

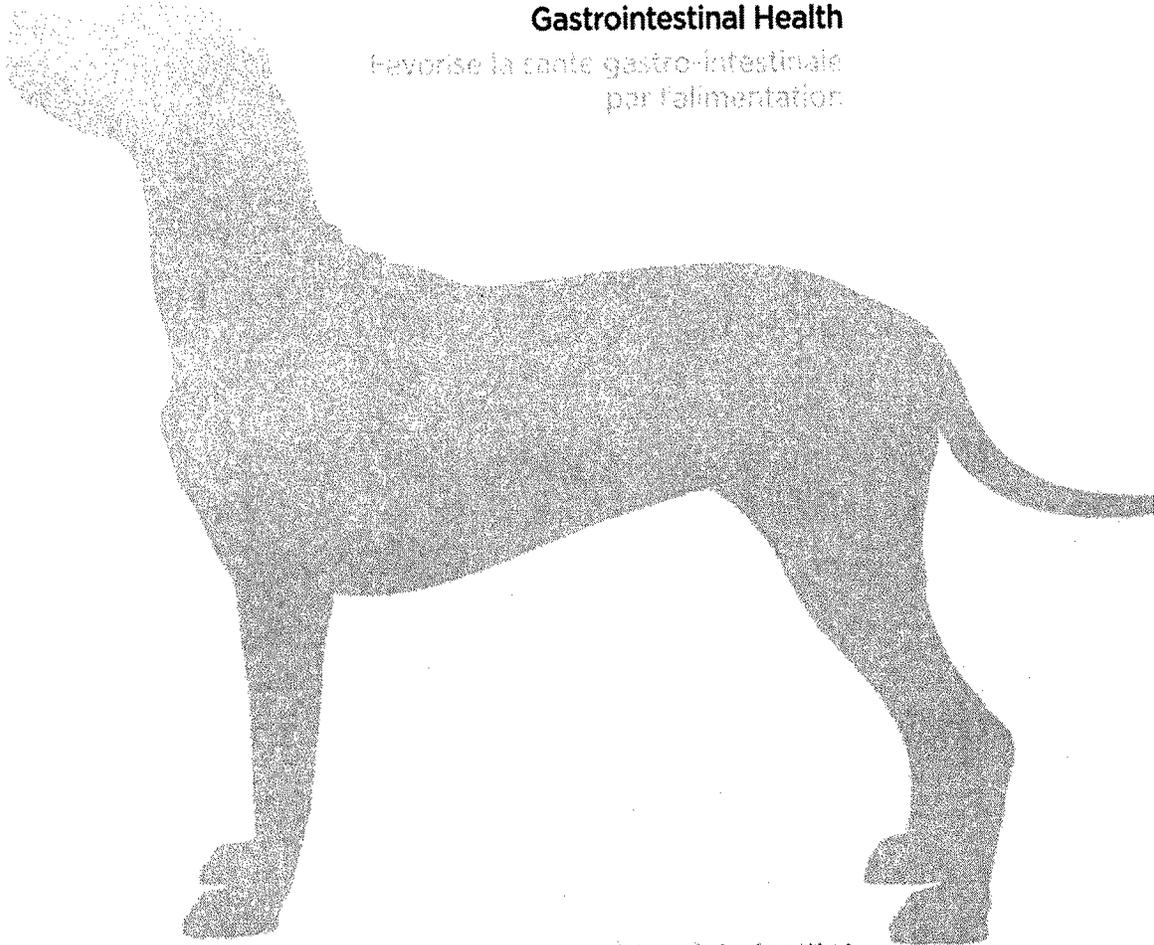
ROYAL CANIN

ROYAL CANIN

EXHIBIT H

Nutritional Management of Gastrointestinal Health

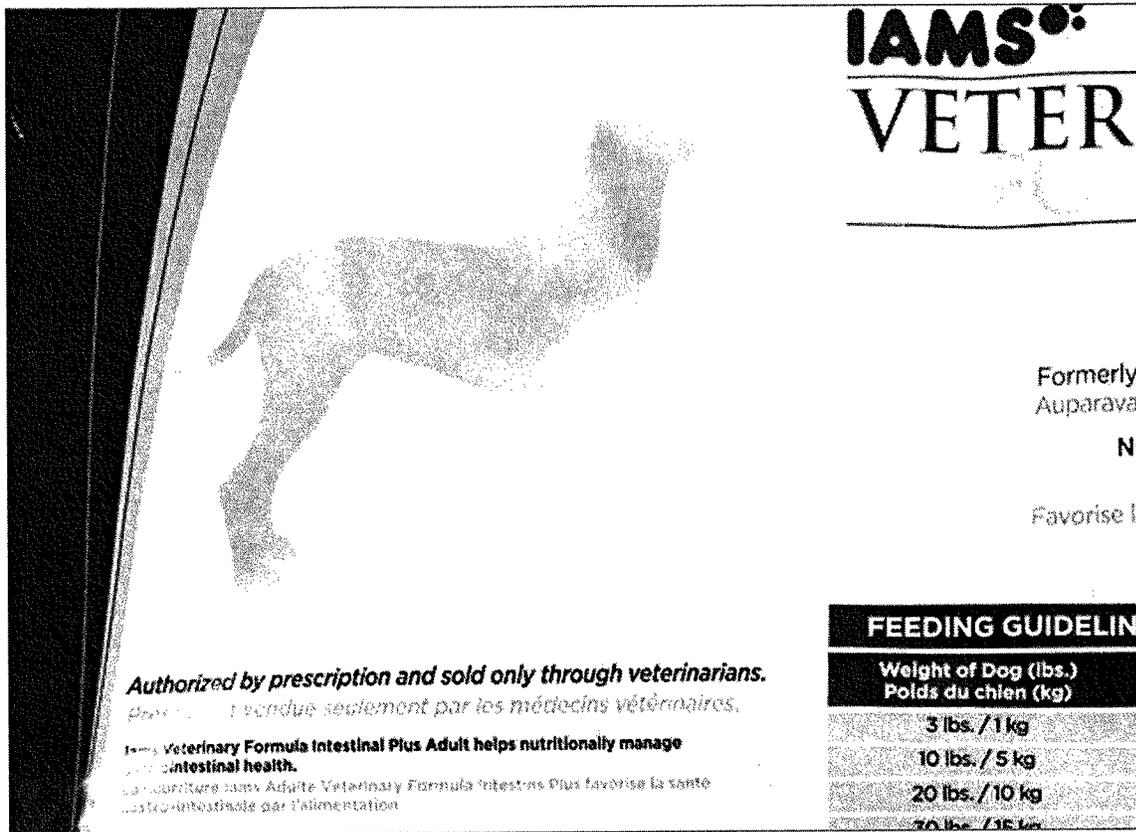
Favorise la sante gastro-intestinale
par l'alimentation.



Dog food prescribed and sold only by veterinarians for nutritional management of gastrointestinal challenges, plus support of overall health & well-being.

Nourriture pour chiens prescrite et vendue seulement par les medecins veterinaires pour la gestion par l'alimentation des troubles Gastro-intestinaux, en plus de favoriser la sante et le bien-etre en general.

NET WT. / POIDS NET : 30 lbs. (13,61 kg)



IAMS®
VETER

Formerly
Auparava
Nu
Favorise la

Authorized by prescription and sold only through veterinarians.
Prescription uniquement vendue seulement par les médecins vétérinaires.

IAMS Veterinary Formula Intestinal Plus Adult helps nutritionally manage intestinal health.
La nourriture IAMS Adulte Veterinary Formula Intestinal Plus favorise la santé intestinale par l'alimentation.

FEEDING GUIDELINE	
Weight of Dog (lbs.)	Poids du chien (kg)
3 lbs. / 1 kg	
10 lbs. / 5 kg	
20 lbs. / 10 kg	
30 lbs. / 15 kg	

INGREDIENTS: Corn Grits, Brewers Rice, Chicken By-Product Meal, Chicken, Fish Meal (source of fish oil), Dried Beet Pulp, Chicken Flavor, Dried Egg Product, Chicken Fat (preserved with mixed Tocopherols, a source of Vitamin E), Brewers Dried Yeast, Fructooligosaccharides, Calcium Carbonate, Potassium Chloride, Monosodium Phosphate, Fish Oil (preserved with mixed Tocopherols, a source of Vitamin E), Sodium Hexametaphosphate, Choline Chloride, Vitamin E Supplement, Flax Meal, DL-Methionine, Minerals (Ferrous Sulfate, Zinc Oxide, Manganese Sulfate, Copper Sulfate, Manganous Oxide, Potassium Iodide), Vitamins (Ascorbic Acid, Vitamin A Acetate, Calcium Pantothenate, Biotin, Thiamine Mononitrate (source of vitamin B1), Vitamin B12 Supplement, Niacin, Riboflavin Supplement (source of vitamin B2), Inositol, Pyridoxine Hydrochloride (source of vitamin B6), Vitamin D3 Supplement, Folic Acid), Ethoxyquin (a preservative), Rosemary Extract.

This product is intended for intermittent feeding only, or as directed by your veterinarian.

Your veterinarian will recommend the IAMS Veterinary Formula that best matches the health needs of your dog. When deemed appropriate by your veterinarian, your dog may be transitioned to an appropriate IAMS Premium Protection®, IAMS® or Eukanuba® dog formula.

EXHIBIT I



VETERINARY
EXCLUSIVE
EXCLUSIVEMENT CHEZ
LES VÉTÉRINAIRES
EXCLUSIVO EN
VETERINARIAS



PURINA
PRO PLAN[®]
VETERINARY
DIETS

UR URINARY st/ox[®]
FELINE FORMULA | FORMULE FELINE | FÓRMULA FELINE

[Vertical text on the right edge of the page, likely bleed-through from the reverse side of the document. It is mostly illegible due to the high contrast and orientation.]

EXHIBIT J

VETERINARI EXCLUSIVO
EXCLUSIVO PARA VETERINARIOS
VETERINARIJ EXCLUSIEFMENTE



**PRESCRIPTION
DIET™**

Digestive/Weight/ Glucose Management

Gestión de glucosa/digestión de la digestión / Manejo digestivo del peso y de la glucosa

w/d™



CLINICAL NUTRITION

Helps manage glucose & weight and improves digestion

Aide à gérer le glucose et le poids et améliore la digestion

Ayuda a manejar la glucosa y el peso y mejora la digestión



Chicken Flavor

Sabor de pollo
Sabor a pollo

EXHIBIT K

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P&G Pet Care

Pro-Pet

Simmons Foods

Sunshine Mills

Texas Farm Products

November 8, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-D-0755 - Draft Compliance Policy Guide Sec. 690.150 on Labeling and Marketing of Nutritional Products Intended for Use To Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats

The Pet Food Institute (PFI) thanks the U.S. Food and Drug Administration for the opportunity to submit comments regarding the draft Compliance Policy Guide (CPG) Section 690.150 published on September 10, 2012. PFI represents the companies that make over 98% of U.S. cat and dog food. More than half of U.S. households own a dog or cat, and the U.S. pet food industry supports the health and wellbeing of 84 million pet cats and 74 million pet dogs in the United States. Most pet food products on the market are designed to fulfill the nutritional needs of cats or dogs (i.e., are "complete and balanced"). Complete and balanced pet food products are the culmination of decades of research in the area of canine and feline nutrition and are developed with healthy animals in mind.

The unfortunate reality is that some pets develop health issues over the course of their lives, some of which are chronic. Careful management of food and nutrient intake has offered a means to provide nutritional support for the companion animal population since the early days of development of therapeutic products in 1948. Therapeutic animal diets have provided nutritional support for untold numbers of pet dogs and cats, which in turn provide health benefits to their owners.

Therapeutic animal diets are designed to be fed at the direction of a veterinarian, and it is beneficial for the veterinarian to monitor the performance of a pet on a particular therapeutic diet. Some therapeutic pet foods may not be nutritionally complete and balanced by design and could cause nutritional deficiencies or imbalances if fed to a healthy pet for an extended time. Nevertheless, such diets are appropriate when fed to a pet experiencing a health issue for which a given product was designed.

We suggest a change in the title of the Compliance Policy Guide and language regarding products "intended to diagnose, cure, mitigate, treat or prevent disease". These five terms are used by the FDA in statutory language to define a drug. The types of products described in this draft compliance policy guide are not drugs. Instead they are foods intended to assist in the nutritional

management of pets with certain health conditions. For these reasons, PFI feels a more appropriate title and description of these types of products is: "Nutritional Products Intended for the Dietary Management of Dogs and Cats with Health Conditions."

PFI appreciates the consideration FDA has given to recognizing the benefits that therapeutic diets provide to cats and dogs in less than ideal health condition. The industry is confident that FDA will continue to exercise enforcement discretion with respect to these products, and that therefore therapeutic products will remain on the market as a viable option for veterinarians to prescribe for the dietary management of dogs and cats with specific health conditions. PFI and its member companies support FDA's intent to protect pets and their owners from products that make unwarranted and unsupported drug claims that could harm the pet or waste consumer money. However, therapeutic diets can play an important role in the dietary management of certain health conditions.

We respectfully believe that FDA underestimates the burden of annual reporting in regard to only five companies being affected by the draft CPG. It may be true that only five companies are selling products through veterinarians, but based upon the overall concern, the number of companies selling these products in pet stores or other retail environments is more numerous. PFI feels that FDA should include any company making a product labeled that it is designed to diagnose, cure, mitigate, treat, or prevent disease in dogs and cats in the burden estimate for this draft CPG.

The key purpose of therapeutic animal diets is and always has been nutritional support for dogs or cats with specific diseases or conditions where nutritional needs are compromised or altered due to the condition. They are intended for the dietary management of these diseases or conditions and may or may not be nutritionally complete and balanced, based upon the formulation. PFI requests that FDA clarify in the "Background" section that the CPG is intended to apply to therapeutic pet food products, regardless of whether they are nutritionally complete and balanced or designed for intermittent feeding.

The following comments relate to specific sections of the draft Compliance Policy Guide. Section headings from the draft CPG are in bold typeface followed by PFI's input.

Section "III. Discussion; A. Appropriate Use of Product"

PFI agrees with these statements. These products should only be available to the public through licensed veterinarians with whom the purchaser has a valid Veterinary-Client-Patient Relationship (VCPR) as defined by the American Veterinary Medical Association (AVMA)

Section "III. Discussion; B. Availability of Product Labeling to the General Public"

PFI encourages FDA to allow statements on a label or labeling regarding the dietary management of specific conditions or diseases in order to assist veterinarians in prescribing appropriate therapeutic animal diets.

Section “III. Discussion; C. Feed Ingredients”

PFI encourages FDA to explain that there are two methods by which GRAS can be achieved: through “self-determination” and through “notification.”

We urge FDA to reference not just the 2012 AAFCO *Official Publication*, but future editions as well when considering regulatory actions against undefined feed ingredients. AAFCO publishes its *Official Publication* annually, and each new edition generally includes newly defined or redefined ingredients. Referencing the 2012 AAFCO *Official Publication* in perpetuity would cause FDA’s regulatory actions to get out of synch with the latest regulatory standards for pet food ingredients. Additionally, Regulation PF5(4) in the current 2012 AAFCO *Official Publication* specifies that the common or usual name of the ingredients shall be used for any ingredient for which no name and definition has been established.

PFI also suggests that it would be helpful to industry and regulators to include a notation about approved color additives in this section, as those components are not covered in this draft Compliance Policy Guide.

Section “III. Discussion; D. Drug Listing and Manufacturer Registration”

PFI agrees that no drug registration or drug listing should be required.

Section “IV. Enforcement Policy; 1. The product is made available to the public only through licensed veterinarians or through retail or internet sales to individuals purchasing the product under the direction of a veterinarian.”

PFI agrees with this requirement. Internet retailers selling therapeutic pet food should have a licensed veterinarian on staff along with a requirement that the veterinarian of the pet owner is consulted by the internet retail veterinarian on staff to assure the right product is purchased.

Section “IV. Enforcement Policy; 2. The product is not marketed as an alternative to approved new animal drugs.”

We understand that the FDA intends to prohibit marketing materials that promote a therapeutic pet food in place of or instead of an approved new animal drug. PFI believes this intent should not limit the availability of a nutritional product for conditions that are also treated via drugs. It is important to remember that the primary function of therapeutic animal diets is to support the animal’s health by providing food with specific nutritional formulas working through the animal’s nutritional pathways. Therefore, there is no conflict as the veterinarian can recommend a new animal drug and/or a therapeutic food in the medical and nutritional management of the patient.

Pet food manufacturers should be allowed to share with veterinary professionals all indications and contraindications that may exist. Such information may be critical to safe use, and therefore such communication should not be seen as “marketing” a product as an alternative to an approved new animal drug.

Section “IV. Enforcement Policy; 3. The manufacturer is registered under section 415 of the FD&C Act.”

PFI suggests that it may be helpful to note that the manufacturer maintains active registration under section 415 of the FD&C Act as there is now a reregistration requirement every two years. FDA might also include the term “bioterrorism” when describing the Section 415 requirements, as this is a term that is often most recognized by companies.

Section “IV. Enforcement Policy; 4. The product’s labeling complies with all food labeling requirements for such products (see 21 CFR Part 501).”

Title 21 CFR Part 501 only pertains to information provided on the product label. It does not address labeling in general. Therefore we would recommend that the statement should be modified to read “The product’s label complies with all food labeling requirements for such products (see 21 CFR Part 501).”

Section “IV. Enforcement Policy; 5. The product does not include indications for a disease claim (e.g., obesity, renal failure) on the label.”

Since therapeutic animal diets are only available to the public through licensed veterinarians or under the direction of a veterinarian, PFI feels that the label should be allowed to denote that a product is intended for the nutritional management of animals with a particular disease state, which is relevant to the appropriate use by a veterinarian. Additionally, PFI believes that referring to the disease state in the product name should be allowed to facilitate proper recommendation by veterinarians, and thus should be acceptable on the label for this purpose. Both of these practices have been common for therapeutic diets for some time and have been helpful to veterinarians. We understand that the FDA is concerned about protecting the consumer from the ability to self-diagnose, but the therapeutic products are intended to be sold under the control of the veterinarian and they, the veterinarian, need to easily see which product by name is appropriate for the pet. PFI also notes that there is confusion among the industry as to which terms are prohibited from use on a therapeutic pet food label.

It is important to consider, for the reasons listed above, (i.e. therapeutic products are recommended to pet owners by licensed veterinarians and are not available to the public at large) the label itself is not a tool to market or advertise to the public.

Since FDA has existing pre-market authorization procedures for several types of claims (e.g., hairball, urinary, plaque/tartar), PFI expects the agency would explicitly exclude these types of claims from this CPG requirement.

Lastly, PFI hopes the agency would not include products designed to promote maintenance of a healthy weight or weight loss (e.g., “weight management”, “weight loss”, “reduced calorie” and similarly marketed pet food products) in this guidance. Weight loss products can be a tool to enable pet owners to reduce the weight of a pet that has exceeded its ideal body condition, whether purchased at a pet owner’s discretion or at the direction of a veterinarian. Weight management products have been sold at retail for many years and are not designed nor required to be sold by the direction of a veterinary recommendation. Furthermore the Association of American Feed Control Officials (AAFCO) has developed rules for claims and

descriptive terms such as “lite”, “reduced calorie”, “lean” and “low fat” that creates consistency in the marketplace. PFI believes that FDA does not intend to alter the legal status of these types of products, particularly products designed for weight loss, but the mention of “obesity” in the CPG may create confusion and uncertainty in the marketplace. It would be helpful to pet owners, veterinarians and pet food companies if FDA were to clarify that the CPG is not meant to, nor does it, alter the legal status of pet food products designed to promote healthy weight maintenance, weight loss, or that are marketed as “lite”, “reduced calorie”, “lean,” “low fat”, etc.

Section “IV. Enforcement Policy; 6. Distribution of labeling and promotional materials with any disease claims for the product is limited so that it is provided only to veterinary professionals.”

PFI expects that the term “distribution” includes both print and digital distribution of materials.

Patient information brochures created by pet food manufacturers to be distributed only to veterinary professionals should be excluded from this requirement.

Section “IV. Enforcement Policy; 7. Electronic resources for the dissemination of labeling information and promotional materials are secured so that they are available only to veterinary professionals.”

General product information should be available to the public, with more specific information obtainable through a secure site available only to veterinarians. If labeling includes no disease claims, then companies should be able to provide truthful information to consumers about therapeutic products that are available through veterinarians. Truthful information present on the label and that is in compliance with this CPG should be allowed to be communicated to consumers.

Section “IV. Enforcement Policy; 8. The product contains only ingredients that are GRAS ingredients, approved food additives, or feed ingredients defined in the 2012 Official Publication of the Association of American Feed Control Officials.”

As previously mentioned in this public comment under Section III. Discussion; C. Feed Ingredients, PFI encourages FDA to explain that there are two methods by which GRAS can be achieved: through “self-determination” and through “notification.”

We urge FDA to reference not just in the 2012 AAFCO *Official Publication*, but future editions as well when considering regulatory actions against undefined feed ingredients. AAFCO publishes its *Official Publication* annually, and each new edition generally includes newly defined or redefined ingredients. Referencing the 2012 AAFCO *Official Publication* in perpetuity would cause FDA’s regulatory actions to get out of synch with the latest regulatory standards for pet food ingredients.

Additionally, Regulation PF5(4) in the current 2012 AAFCO *Official Publication* specifies that the common or usual name of the ingredients shall be used for any ingredient for which no name and definition has been established.

PFI also suggests that it would be helpful to industry and regulators to include a notation about approved color additives in this section.

Section "IV. Enforcement Policy; 9. The label and labeling of the product is not false and misleading in other respect."

PFI agrees that the label and labeling should not be false and misleading.

Comments on "Priority for enforcement attention"

Considering that these are meant to be in priority order, PFI would suggest that higher priority be given for those products that are made directly available to the public circumventing the veterinarian (#4).

PFI again would like to thank the agency for the opportunity to submit public comment on this draft Compliance Policy Guide. We are encouraged by and support FDA's efforts to prevent consumer fraud and hope the same philosophy will be uniformly applied to other pet products, including dietary supplements.

We look forward to continuing to work with the FDA to develop any further needed language to deal with this important category of pet food. Please do not hesitate to contact PFI for any further assistance or for any needed discussion.

Sincerely,

A handwritten signature in black ink, appearing to read "Duane Ekedahl", with a long horizontal flourish extending to the right.

Duane Ekedahl
President Pet Food Institute